

EXHIBIT B46

Shawn Levy, Ph.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION

Case No. 16-2738
(FLW) (LHG)

THIS DOCUMENT RELATES TO
ALL CASES

MDL Docket No. 2738

Friday, January 11, 2019

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The video deposition of SHAWN LEVY, Ph.D.,
taken pursuant to notice, was held at the
Embassy Suites Huntsville, 850 Monroe Street
S.W., Huntsville, Alabama, commencing at
approximately 9:04 a.m., on the above date,
before Lois Anne Robinson, Registered Diplomat
Reporter, Certified Realtime Reporter, and
Notary Public for the State of Alabama.

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<p>1 INDEX - (continued)</p> <p>2 Deposition Exhibit Number 15 190</p> <p>3 NTP study</p> <p>4 Deposition Exhibit Number 16 192</p> <p>5 2014 Citizens Petition to FDA</p> <p>6 Deposition Exhibit Number 17 208</p> <p>7 Buz'Zard study</p> <p>8 Deposition Exhibit Number 18 218</p> <p>9 "Perineal Talc Use and Ovarian Cancer," by Ross Penninkilampi</p> <p>10 Deposition Exhibit Number 19 249</p> <p>11 Heller article</p> <p>12 Deposition Exhibit Number 20 270</p> <p>13 Merritt paper - "Talcum Powder Chronic Pelvic Inflammation</p> <p>14 and NSAIDs in Relation to the Risk of Epithelial Ovarian</p> <p>15 Cancer"</p> <p>16 Deposition Exhibit Number 21 326</p> <p>17 Nunes article</p> <p>18 Deposition Exhibit Number 22 367</p> <p>19 Park article</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 A Good morning.</p> <p>2 Q My name is Alli Brown. I represent</p> <p>3 Johnson & Johnson, and I'll start with some</p> <p>4 questions for you here today.</p> <p>5 Dr. Levy, have you ever been deposed</p> <p>6 before?</p> <p>7 A Yes.</p> <p>8 Q And tell me, how many times?</p> <p>9 A In a setting like this, once.</p> <p>10 Q Okay. What was the nature of that</p> <p>11 deposition?</p> <p>12 A It was a patent litigation case.</p> <p>13 Q Were you serving as an expert witness</p> <p>14 in that case?</p> <p>15 A I was.</p> <p>16 Q Were you hired by the plaintiffs or the</p> <p>17 defendants?</p> <p>18 A The plaintiffs.</p> <p>19 Q And, just generally, what were the</p> <p>20 issues in that case?</p> <p>21 A It was entirely focused on evaluation</p> <p>22 of prior art in the genomic space.</p> <p>23 Q And any time --</p> <p>24 And do you remember the name of that</p>
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<p>1 VIDEOGRAPHER:</p> <p>2 We are now on the record. My name is</p> <p>3 Julie Robinson. I'm a videographer representing</p> <p>4 Golkow Litigation Services.</p> <p>5 Today's date is January 11th, 2019, and</p> <p>6 the time is 9:04 a.m.</p> <p>7 This video deposition is being held in</p> <p>8 Huntsville, Alabama, in the matter of</p> <p>9 Johnson & Johnson Talcum Powder Product Marketing,</p> <p>10 Sales Practices, and Products Liability</p> <p>11 Litigation, MDL Docket Number 2738.</p> <p>12 The deponent is Dr. Shawn Levy.</p> <p>13 Counsel will be noted on the</p> <p>14 stenographic record.</p> <p>15 The court reporter is Lois Robinson,</p> <p>16 who will now swear in the witness.</p> <p>17 SHAWN LEVY, Ph.D.,</p> <p>18 the witness, after having first been</p> <p>19 duly sworn to tell the truth, the whole truth,</p> <p>20 and nothing but the truth, was examined and</p> <p>21 testified as follows:</p> <p>22 EXAMINATION</p> <p>23 BY MS. BROWN:</p> <p>24 Q Good morning, Dr. Levy.</p>	<p>1 case, by the way?</p> <p>2 A I don't. It was, gosh, twelve years</p> <p>3 ago or so.</p> <p>4 Q I see.</p> <p>5 Did that case go to trial?</p> <p>6 A Not that I'm aware of.</p> <p>7 Q Have you ever testified at trial?</p> <p>8 A I have not.</p> <p>9 Q Okay. And other than that one patent</p> <p>10 case you just described for us, were there other</p> <p>11 depositions that you've given?</p> <p>12 A No.</p> <p>13 Q And I think, when you started to answer</p> <p>14 the question in the beginning, you said "in a</p> <p>15 setting like this." Is there another time, in</p> <p>16 your mind, where you've given testimony under</p> <p>17 oath?</p> <p>18 A No, not under oath. That's why I</p> <p>19 was --</p> <p>20 So I've had a number of meetings, all</p> <p>21 limited to the patent space of mainly prior art</p> <p>22 discussions, where there's been representatives</p> <p>23 from both sides where we were having a</p> <p>24 discussion. But it wasn't a formal deposition</p>

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<p>1 with a court reporter, under oath, et cetera.</p> <p>2 Q Understood.</p> <p>3 So this would then be the second time</p> <p>4 you've been deposed in a setting like this.</p> <p>5 A Correct.</p> <p>6 Q Is that fair?</p> <p>7 Okay. So a few ground rules that you</p> <p>8 may already be familiar with from your prior</p> <p>9 experience. First, we'll try not to speak over</p> <p>10 each other. Is that fair?</p> <p>11 A That's fair.</p> <p>12 Q That way, our court reporter can get</p> <p>13 down all my questions and all your answers.</p> <p>14 Okay?</p> <p>15 A (Nods affirmatively.)</p> <p>16 Q If you don't understand a question of</p> <p>17 mine, will you let me know?</p> <p>18 A I will.</p> <p>19 Q Okay. Try to verbalize your answers,</p> <p>20 too, so our court reporter can take them down.</p> <p>21 Okay?</p> <p>22 A Understood.</p> <p>23 Q Okay. If you need a break, let me</p> <p>24 know, and we'll be happy to accommodate you.</p>	<p>1 with.</p> <p>2 Q Okay. In front of you is the</p> <p>3 plaintiffs' lawyer's laptop. Is that right?</p> <p>4 A That's right.</p> <p>5 Q Okay. And what is contained on the</p> <p>6 plaintiffs' lawyer's laptop?</p> <p>7 MS. O'DELL:</p> <p>8 I think I'd probably be better to speak</p> <p>9 to it.</p> <p>10 MS. BROWN:</p> <p>11 No, no. Let's get it from the witness,</p> <p>12 and then if you want to make a statement for the</p> <p>13 record, of course.</p> <p>14 Q Let's -- let's get your understanding</p> <p>15 of what's on this laptop in front of you.</p> <p>16 A Other than what's on the USB drive that</p> <p>17 I've been using, I -- I don't have any knowledge</p> <p>18 of what's on it.</p> <p>19 Q Okay. Do you know what's on the USB</p> <p>20 drive?</p> <p>21 A I do.</p> <p>22 Q What's that?</p> <p>23 A It's a collection of literature cited</p> <p>24 in reliance literature list that -- from</p>
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<p>1 Do you understand you're under oath</p> <p>2 here today, same as if you were in a court of</p> <p>3 law?</p> <p>4 A I do.</p> <p>5 Q Okay. I am --</p> <p>6 And, before we get started, Doctor, I</p> <p>7 see you have a couple of items in front of you,</p> <p>8 and I want to identify what we have for the</p> <p>9 record.</p> <p>10 To your right is an iPad that is</p> <p>11 showing the realtime of my questions and your</p> <p>12 answers. Will you be using that to assist you in</p> <p>13 your testimony here today?</p> <p>14 A Yes.</p> <p>15 Q Okay. In front of you you have a</p> <p>16 laptop computer.</p> <p>17 A (Nods affirmatively.)</p> <p>18 Q Will you be using that to assist you in</p> <p>19 your testimony?</p> <p>20 A Yes.</p> <p>21 Q And tell me, is this your laptop?</p> <p>22 A It is not.</p> <p>23 Q Okay. Whose laptop is it?</p> <p>24 A The -- the attorneys I've been working</p>	<p>1 my -- from my report.</p> <p>2 Q Did you put together the items that are</p> <p>3 contained on the USB drive that you have in front</p> <p>4 of you?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A Yes.</p> <p>8 MS. BROWN:</p> <p>9 Q Is that your USB drive?</p> <p>10 A No. I put together the list.</p> <p>11 As far as who moved the files and</p> <p>12 organized the files on the USB, that, I don't</p> <p>13 know.</p> <p>14 Q Okay. Are all of the files on that USB</p> <p>15 drive documents that you considered in connection</p> <p>16 with your opinion in this case?</p> <p>17 A They are.</p> <p>18 Q Any other materials in front of you</p> <p>19 that you'll be using to assist you in your</p> <p>20 testimony here today?</p> <p>21 A There's a -- I have a hard copy of my</p> <p>22 report.</p> <p>23 Q Did you prepare that hard copy binder?</p> <p>24 A No.</p>

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<p>1 Q Who -- who did?</p> <p>2 A My -- the -- the attorneys I've been</p> <p>3 working with. So I -- they -- they provided the</p> <p>4 printout and the nice binder that it's in.</p> <p>5 Q Okay. Did you, Doctor, make any notes</p> <p>6 on the report that you have in front of you?</p> <p>7 A No.</p> <p>8 Q Okay. I'm gonna hand you what we have</p> <p>9 marked as Exhibit 1 to your deposition, which is</p> <p>10 a notice of your deposition.</p> <p>11 (DEPOSITION EXHIBIT NUMBER 1</p> <p>12 WAS MARKED FOR IDENTIFICATION.)</p> <p>13 MS. BROWN:</p> <p>14 Q And I'll ask, is this something that</p> <p>15 you have ever seen before?</p> <p>16 A Yes.</p> <p>17 Q When did you see it?</p> <p>18 A I'd have to review my email, but it was</p> <p>19 some -- sometime ago, some weeks ago.</p> <p>20 Q Okay. Have you brought any --</p> <p>21 And you understand that this Notice of</p> <p>22 Deposition that we've marked as Exhibit 1</p> <p>23 requests that you bring certain documents with</p> <p>24 you here today?</p>	<p>1 Thank you.</p> <p>2 -- by marking these, and I'll ask you</p> <p>3 some questions about what we have.</p> <p>4 (DEPOSITION EXHIBIT NUMBER 3</p> <p>5 WAS MARKED FOR IDENTIFICATION.)</p> <p>6 MS. BROWN:</p> <p>7 Q I'll mark as Exhibit 3 to your</p> <p>8 deposition two invoices counsel for plaintiffs</p> <p>9 just handed me, one dated May 2nd, 2018, and the</p> <p>10 other dated January 8th, 2019. And we only have</p> <p>11 one copy, so let me hand it to you and ask you,</p> <p>12 are these invoices that you created, Doctor?</p> <p>13 A They are.</p> <p>14 Q Okay. And I want to take that back for</p> <p>15 one second.</p> <p>16 Looks like the first entry on your</p> <p>17 invoice is dated May 16th, 2017. Does that sound</p> <p>18 right to you?</p> <p>19 A That sounds right.</p> <p>20 Q When were you first approached about an</p> <p>21 involvement in this case?</p> <p>22 A Earlier in 2017.</p> <p>23 Q Okay. And who approached you?</p> <p>24 A Leigh and Jennifer. I'd have to verify</p>
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<p>1 A Yes.</p> <p>2 Q Okay.</p> <p>3 MS. O'DELL:</p> <p>4 Let me just insert for the record,</p> <p>5 we've objected to certain requests contained in</p> <p>6 the notice, and objections have been served, and</p> <p>7 materials have been brought to this deposition</p> <p>8 consistent with those objections.</p> <p>9 MS. BROWN:</p> <p>10 And we are in receipt of your</p> <p>11 objections.</p> <p>12 Q And your counsel for the plaintiffs</p> <p>13 represented that some materials have been brought</p> <p>14 to the deposition. Do you have any materials</p> <p>15 with you responsive to this notice?</p> <p>16 A Well --</p> <p>17 MS. O'DELL:</p> <p>18 I'll provide to you invoices that are</p> <p>19 responsive to the Notice, and there are materials</p> <p>20 that Dr. Levy has seen since his report was</p> <p>21 served, and -- and those are copies.</p> <p>22 MS. BROWN:</p> <p>23 Thank you, counsel.</p> <p>24 Q So, Doctor, let's start --</p>	<p>1 in my email whom I may have heard from first.</p> <p>2 Q Okay. And Leigh and Jennifer are</p> <p>3 counsel for plaintiffs in this litigation; is</p> <p>4 that right?</p> <p>5 A That's right.</p> <p>6 Q And did they -- had you known them</p> <p>7 prior to receiving contact early in 2017 --</p> <p>8 A No.</p> <p>9 Q -- from plaintiffs' lawyers?</p> <p>10 A I -- I did not know them.</p> <p>11 Q Did they call you at your place of</p> <p>12 business?</p> <p>13 A I believe the first contact was email.</p> <p>14 But, ultimately, yes.</p> <p>15 Q Okay. And was there any connection,</p> <p>16 meaning did someone refer the plaintiffs' lawyers</p> <p>17 to you, or do you know?</p> <p>18 A I don't know.</p> <p>19 Q Do you have any idea how the</p> <p>20 plaintiffs' lawyers found you?</p> <p>21 A I do not.</p> <p>22 Q Okay. It looks like, Doctor, that</p> <p>23 these two invoices have a total of 33 hours.</p> <p>24 Does that sound right to you?</p>

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<p style="text-align: right;">Page 18</p> <p>1 A It does.</p> <p>2 Q Looks like something's blacked out on</p> <p>3 the second page of the invoices. Do you know</p> <p>4 what that is?</p> <p>5 MS. O'DELL:</p> <p>6 I'll just say that redactions were made</p> <p>7 by counsel. They referenced the subject matter</p> <p>8 of conversations between Dr. Levy and counsel,</p> <p>9 and those have been redacted because of work</p> <p>10 product privilege.</p> <p>11 MS. BROWN:</p> <p>12 Okay.</p> <p>13 Q Is it fair, Doctor, that you've spent a</p> <p>14 total of 33 hours forming your opinions in this</p> <p>15 case?</p> <p>16 A That's fair.</p> <p>17 Q Okay. Do you have any additional</p> <p>18 invoices that you plan to submit to the lawyers</p> <p>19 for the plaintiffs?</p> <p>20 A Yes.</p> <p>21 Q Okay. And can you ballpark for me how</p> <p>22 much additional time you've spent since the last</p> <p>23 entry here, which appears to be December 12th,</p> <p>24 2018?</p>	<p style="text-align: right;">Page 20</p> <p>1 Your report in this case was served in</p> <p>2 November of 2018; correct?</p> <p>3 A Correct.</p> <p>4 Q Fair to say, then, that Exhibit 4,</p> <p>5 which you saw for the first time in December of</p> <p>6 2018, did not inform the opinions contained in</p> <p>7 your report?</p> <p>8 A That's correct.</p> <p>9 Q Okay. Did the -- does Exhibit 4</p> <p>10 contain any information regarding chronic</p> <p>11 inflammation as the proposed mechanism of ovarian</p> <p>12 cancer induced by talc?</p> <p>13 A I don't believe it does. I'd have to</p> <p>14 review -- take a look at it to be sure.</p> <p>15 MS. O'DELL:</p> <p>16 And if you need to look at it, I'm sure</p> <p>17 counsel will hand it to you.</p> <p>18 MS. BROWN:</p> <p>19 Q I'm handing you, Doctor --</p> <p>20 MS. O'DELL:</p> <p>21 Excuse me. If you need to look at it</p> <p>22 to answer that question, you may.</p> <p>23 A To be sure I'm accurate in my answer,</p> <p>24 I'd like to take a look at that.</p>
<p style="text-align: right;">Page 19</p> <p>1 A There's probably another -- not</p> <p>2 including this morning -- roughly 15 hours.</p> <p>3 Okay. I'll hand you, Doctor, what we</p> <p>4 have marked as Exhibit 4 to your deposition.</p> <p>5 This is another document counsel for the</p> <p>6 plaintiffs just handed me.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 4</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q Would you identify that for the record,</p> <p>11 please.</p> <p>12 A This is a printed copy from a website</p> <p>13 from the government of Canada discussing their</p> <p>14 draft screening assessment of talc.</p> <p>15 Q Okay. Is that something you've seen</p> <p>16 before today?</p> <p>17 A Yes.</p> <p>18 Q When did you see it first?</p> <p>19 A Sometime in December.</p> <p>20 Q Did the lawyers for plaintiffs give it</p> <p>21 to you?</p> <p>22 A They did.</p> <p>23 Q Okay. Your report in this case --</p> <p>24 Can I have that back?</p>	<p style="text-align: right;">Page 21</p> <p>1 MS. BROWN:</p> <p>2 Q Sure. Sitting here --</p> <p>3 Hold on.</p> <p>4 Sitting here today, you're not aware if</p> <p>5 Exhibit 4 contains any information regarding the</p> <p>6 proposed mechanism of chronic inflammation as a</p> <p>7 cause for ovarian cancer?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the question.</p> <p>10 If you need to see the document,</p> <p>11 Doctor, you may ask for it.</p> <p>12 A Yeah. I'm not -- I'm not able to</p> <p>13 answer it accurately without seeing the document.</p> <p>14 (DEPOSITION EXHIBIT NUMBER 5</p> <p>15 WAS MARKED FOR IDENTIFICATION.)</p> <p>16 MS. BROWN:</p> <p>17 Q Okay. Handing you what we've marked as</p> <p>18 Exhibit 5, would you tell me what that is,</p> <p>19 Doctor?</p> <p>20 A This is another document from the</p> <p>21 government -- government of Canada discussing the</p> <p>22 potential risk of lung effects and ovarian cancer</p> <p>23 from talc.</p> <p>24 Q Is Exhibit 5 a final document, do you</p>

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<p>1 know?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A Yeah. That -- I don't -- I don't have</p> <p>5 the information available to answer that</p> <p>6 accurately.</p> <p>7 MS. BROWN:</p> <p>8 Q Have you seen Exhibit 5 prior to this</p> <p>9 morning?</p> <p>10 A I have.</p> <p>11 Q When did you first see Exhibit 5?</p> <p>12 A Similar in time to the earlier report</p> <p>13 or this -- yes. Similar in time to the</p> <p>14 earlier -- to the same document from Exhibit 4.</p> <p>15 Q To the best of your recollection,</p> <p>16 Doctor, you first saw Exhibit 5 after completing</p> <p>17 your report in this matter; is that right?</p> <p>18 A That is right.</p> <p>19 Q Fair to say, then, that Exhibit 5 did</p> <p>20 not inform the opinions contained in your MDL</p> <p>21 report?</p> <p>22 A That's correct.</p> <p>23 Q Handing you, Doctor, what we've marked</p> <p>24 as Exhibit 6 to your deposition, another document</p>	<p>1 Q Does Exhibit 6 contain any information</p> <p>2 regarding the proposed mechanism of chronic</p> <p>3 inflammation?</p> <p>4 A It does in reference, I believe. I'm</p> <p>5 reminding myself if -- if it shared the same</p> <p>6 materials that I had referenced in my report.</p> <p>7 So, yes, it does.</p> <p>8 Q Are you looking at a particular page,</p> <p>9 Doctor?</p> <p>10 A I am.</p> <p>11 Q And would you identify that for the</p> <p>12 record.</p> <p>13 A I'm looking at page 23, beginning at</p> <p>14 line 220.</p> <p>15 Q And what information does Exhibit 6 at</p> <p>16 page 23 contain regarding chronic inflammation?</p> <p>17 A It discusses inflammation of the</p> <p>18 epithelial ovarian surfaces in animal models and</p> <p>19 provides two different references.</p> <p>20 Q And were those references information</p> <p>21 you considered in forming your opinions in this</p> <p>22 case?</p> <p>23 A Let me make sure of that.</p> <p>24 Yes.</p>
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<p>1 counsel provided, counsel for plaintiffs provided</p> <p>2 in response to your deposition notice.</p> <p>3 (DEPOSITION EXHIBIT NUMBER 6</p> <p>4 WAS MARKED FOR IDENTIFICATION.)</p> <p>5 MS. BROWN:</p> <p>6 Q Would you identify for the record</p> <p>7 Exhibit 6?</p> <p>8 A So this is a draft manuscript or</p> <p>9 preprint manuscript that's been submitted for</p> <p>10 peer review discussing the systematic review and</p> <p>11 meta-analysis of the association between perineal</p> <p>12 use of talc and risk of ovarian cancer.</p> <p>13 Q Had you seen Exhibit 6 prior to this</p> <p>14 morning?</p> <p>15 A Yes.</p> <p>16 Q When did you first see Exhibit 6?</p> <p>17 A It was in December as well.</p> <p>18 Q Exhibit 6 did not inform your opinions</p> <p>19 in this matter. Fair?</p> <p>20 A They did not inform the content of the</p> <p>21 report.</p> <p>22 Q Have you reviewed and analyzed Exhibit</p> <p>23 6 since December?</p> <p>24 A I have.</p>	<p>1 Q And would you state what they are for</p> <p>2 the record, please?</p> <p>3 A One reference is T.C. Hamilton, et al.,</p> <p>4 The British Journal of Experimental Pathology,</p> <p>5 from 1984.</p> <p>6 And the other reference is "The</p> <p>7 Pathology of Ovarian" -- "The Pathology of</p> <p>8 Ovarian Cancer Precursors," which is a review of</p> <p>9 R.E. Scully in the Journal of Cellular</p> <p>10 Biochemistry, and that is a supplement from 1995.</p> <p>11 The latter is not referenced in my report.</p> <p>12 Q Have you reviewed the Scully paper in</p> <p>13 connection with your opinions in this matter?</p> <p>14 A Not specifically, no.</p> <p>15 Q You have, however, reviewed the</p> <p>16 Hamilton paper?</p> <p>17 A Yes.</p> <p>18 Q You would agree that the Hamilton paper</p> <p>19 does not show inflammation leading to neoplastic</p> <p>20 changes in animals?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A I'd have to see the manu- -- or the</p> <p>24 manuscript to answer your specific question</p>

7 (Pages 22 to 25)

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<p>1 regarding neoplasm. 2 MS. BROWN: 3 Q Does the Hamilton paper support your 4 view that chronic inflammation is a plausible 5 mechanism for talc-induced ovarian cancer? 6 A It supports my opinion that 7 inflammation is a component in the progression to 8 ovarian cancer. 9 Q Is it your testimony that the Hamilton 10 paper supports your opinion that chronic 11 inflammation leads to neoplastic changes? 12 A No, not necessarily. 13 Q Okay. Tell me how it is that the 14 Hamilton paper supports your opinion that chronic 15 inflammation can cause ovarian cancer. 16 A Well, the -- so my opinion regarding -- 17 that the role of inflammation in ovarian cancer 18 is not based on a single study, particularly one 19 that is now approaching or is now over 30 years 20 old. 21 Q Okay. Does -- 22 A So it's a -- I reviewed the -- that 23 paper as well as a large number or the totality 24 of the available evidence stretching across many</p>	<p>1 MS. O'DELL: 2 -- paper in order to answer the 3 question -- 4 MS. BROWN: 5 Counsel -- 6 MS. O'DELL: 7 -- you may do that. 8 MS. BROWN: 9 Counsel, he is absolutely entitled to 10 get the paper. We're going to do that. 11 Q Sitting here today, do you recall -- 12 MS. O'DELL: 13 But he is not -- 14 MS. BROWN: 15 It's a fair question. 16 MS. O'DELL: 17 Is it not a fair question. 18 MS. BROWN: 19 I'm not gonna -- 20 MS. O'DELL: 21 He's asking -- 22 MS. BROWN: 23 -- do this with you. 24 MS. O'DELL:</p>
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<p>1 years to develop the opinion that's represented 2 in my report. 3 Q Sure. 4 A And to that opinion is -- no one study 5 or one singular piece of information is the basis 6 of that opinion. 7 Q Okay. But, you know, having reviewed 8 Hamilton, that what Hamilton shows is that the 9 inflammation they saw in the animals was not 10 associated with neoplastic changes. Right? 11 MS. O'DELL: 12 Excuse me. 13 Doctor, if you'd like to -- to pull up 14 Hamilton, you may do that. 15 MS. BROWN: 16 Q And we'll certainly give you time to do 17 that, Doctor. 18 Sitting here today, do you recall that 19 to be the conclusion of Hamilton? 20 MS. O'DELL: 21 Object to the form. 22 You don't -- if you need to see the -- 23 MS. BROWN: 24 Counsel --</p>	<p>1 Yes, you are. If he's asked to see the 2 paper, he gets to look at the paper. Because 3 this is not a situation where you can say, "Oh, 4 I'll show it to you later," ask all these 5 questions, try to get him to answer when he said 6 I want to see the paper and review it. That's 7 the way this works. 8 MS. BROWN: 9 Q Dr. Levy, can you answer the question 10 without looking at the paper? 11 MS. O'DELL: 12 Would you repeat the question just to 13 make sure we've got it? 14 MS. BROWN: 15 Yes. Would you please keep your 16 objections to form in accordance with the federal 17 rules? 18 MS. O'DELL: 19 My objections have been in accordance 20 with the federal rules. 21 MS. BROWN: 22 Q Dr. Levy, my question to you was 23 whether the Hamilton paper, the findings of the 24 Hamilton paper show that chronic inflammation led</p>

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<p>1 to neoplastic changes. Do you recall that</p> <p>2 question?</p> <p>3 A I do recall the question.</p> <p>4 Q Can you answer that question without</p> <p>5 looking at the paper?</p> <p>6 A I would need to look at the paper to</p> <p>7 accurately answer your question.</p> <p>8 Q Absolutely. Do you have a copy on your</p> <p>9 computer?</p> <p>10 A I do.</p> <p>11 Q Okay. We'll mark it, so we're all on</p> <p>12 the same page, as Exhibit 7.</p> <p>13 (DEPOSITION EXHIBIT NUMBER 7</p> <p>14 WAS MARKED FOR IDENTIFICATION.)</p> <p>15 MS. BROWN:</p> <p>16 Q Here's a hard copy, Doctor, if that</p> <p>17 assists you.</p> <p>18 Doctor, looking at the Hamilton article</p> <p>19 that you have in front of you, does that refresh</p> <p>20 you that the authors found no association between</p> <p>21 the talc-induced changes and neoplasm?</p> <p>22 A No. Their -- their conclusions were</p> <p>23 that the talc-induced changes -- specifically</p> <p>24 fibrosis and the papillary changes -- did not</p>	<p>1 Q The Hamilton article does not support</p> <p>2 the theory that chronic inflammation leads to</p> <p>3 neoplastic changes in the ovary. Fair?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A The Hamilton article looked at an</p> <p>7 interval of one month, eighteen months, in a rat</p> <p>8 model. And, so, in the constraints of that</p> <p>9 particular experimental design and given the</p> <p>10 state of the art of the technology at the time,</p> <p>11 the authors did not conclude of a significant</p> <p>12 progression of ovarian cancer. But there's</p> <p>13 clearly limitations in both their experimental</p> <p>14 design and time course of the study to draw wide</p> <p>15 conclusions.</p> <p>16 MS. BROWN:</p> <p>17 Q The conclusions of the Hamilton</p> <p>18 article, Dr. Levy, do not support the hypothesis</p> <p>19 that chronic inflammation from talcum powder</p> <p>20 causes ovarian cancer. Would you agree?</p> <p>21 A I would not.</p> <p>22 Q The authors did not find that the</p> <p>23 inflammation seen in Hamilton led to neoplastic</p> <p>24 changes. True?</p>
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<p>1 appear to be a reaction to talc, but they -- I</p> <p>2 don't see the specific inclusion that you asked</p> <p>3 in the question regarding neoplasm.</p> <p>4 Q I'm looking at page 103, Doctor, the</p> <p>5 first full paragraph that begins "no evidence."</p> <p>6 You with me?</p> <p>7 A One moment. "No evidence of cellular,"</p> <p>8 that paragraph?</p> <p>9 Q Yes.</p> <p>10 And, for the record, that paragraph</p> <p>11 reads, "No evidence of cellular atypia or mitotic</p> <p>12 activity was seen in the nonpapillary areas of</p> <p>13 the surface epithelium of the injected ovaries</p> <p>14 and in no ovary was there any evidence of frank</p> <p>15 neoplasia."</p> <p>16 Correct?</p> <p>17 A It does read that way, yes.</p> <p>18 Q And that was a conclusion of the</p> <p>19 Hamilton article. Correct?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A That was an observation of the Hamilton</p> <p>23 article.</p> <p>24 MS. BROWN:</p>	<p>1 A The authors did not report observing</p> <p>2 neoplastic change over the time course of the</p> <p>3 given study.</p> <p>4 Q Doctor, I'm handing you the report that</p> <p>5 you've served in this case, which we'll mark as</p> <p>6 Exhibit 2.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 2</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q And I'd like you to -- I'd like to</p> <p>11 direct you to page 14. I'd like to direct your</p> <p>12 attention to the last paragraph of -- the last</p> <p>13 sentence -- excuse me -- of the second full</p> <p>14 paragraph that begins "additional studies."</p> <p>15 Do you see that sentence, Doctor?</p> <p>16 A What's the beginning of that paragraph</p> <p>17 so I make sure I'm looking at the right one?</p> <p>18 Q Sure. I'd like to direct you on page</p> <p>19 14 of your report to the second full paragraph</p> <p>20 that begins "In addition to epidemiologic</p> <p>21 evidence."</p> <p>22 Do you see that?</p> <p>23 A I do.</p> <p>24 Q The last paragraph, or the last</p>

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<p style="text-align: right;">Page 34</p> <p>1 sentence of that paragraph in your report reads, 2 "Additional studies have also shown the effects 3 of talc on the immune response." 4 Do you see that sentence? 5 A I do. 6 Q And you cite the Hamilton article for 7 that proposition that we were just reviewing? 8 A Uh-huh. 9 Q True? 10 A True. 11 Q And the talc effects on the immune 12 response that were shown in Hamilton were not 13 effects that the authors observed led to 14 neoplastic changes. Correct? 15 MS. O'DELL: 16 Object to the form. 17 A I'm sorry. I'm not sure I understand 18 your question. 19 MS. BROWN: 20 Q Sure. 21 A Are you asking, if I could clarify, are 22 you -- are you asking if Hamilton is an 23 appropriate reference for the effects of talc on 24 the immune response or are you asking if</p>	<p style="text-align: right;">Page 36</p> <p>1 hypothesis that chronic inflammation leads to 2 cancer in animals. Right? 3 A The -- 4 MS. O'DELL: 5 Object to the form. 6 A The -- those two references were not 7 included in the report to provide the opinion or 8 conclusions that you just described. 9 MS. BROWN: 10 Q Because you know, Doctor, that there's 11 not a single animal study that shows that talc 12 causes changes in animals that leads to cancer; 13 right? 14 MS. O'DELL: 15 Object to the form. 16 A Could you -- could you phrase that 17 question again? Sorry. 18 MS. BROWN: 19 Q There is not a single animal study, 20 Doctor, that supports the opinion that chronic 21 inflammation caused by talc causes ovarian 22 cancer. Is that correct? 23 MS. O'DELL: 24 Object to the form.</p>
<p style="text-align: right;">Page 35</p> <p>1 Hamilton's an appropriate reference for something 2 else? 3 Q In your report, you state that studies, 4 such as Hamilton, have shown effects of talc on 5 the immune response. Correct? 6 A That is correct. 7 Q And you said Hamilton as one of the 8 articles that supports that proposition. True? 9 A Of the immune response, that's true. 10 Q Okay. The immune response that was 11 observed in Hamilton was not an immune response 12 that led to cancer. Right? 13 A As -- as I stated earlier, on the time 14 course of the Hamilton study, the authors did not 15 report specifically to neoplastic change in the 16 rat or conclude or make that conclusion, nor did 17 they conclude that that was not a possibility 18 either. 19 Q And on page 14 of your report you have 20 two additional cites for that proposition; 21 correct? 22 A Correct. 23 Q And you know, Doctor, that neither of 24 those cites, Keskin or NTP, support the</p>	<p style="text-align: right;">Page 37</p> <p>1 A In my review of the literature, there 2 are a number of animal studies that support the 3 opinions in the report regarding the biological 4 plausibility of talc leading to or contributing 5 to neoplastic change. 6 MS. BROWN: 7 Q Are you aware of any animal studies, 8 Doctor, that show talc causing chronic 9 inflammation in animals that leads to neoplastic 10 or cancerous changes in the animals? 11 MS. O'DELL: 12 Object to the form. Compound. 13 A There is one 1971 study that I'm aware 14 of. I would have to review to remember the 15 author. That was an earlier seminal -- or a 16 earlier study that described the role of talcum 17 powder and the inflammatory change within the 18 ovary. 19 MS. BROWN: 20 Q Who's the author of that study, Doctor? 21 A I'm trying to think of where I have 22 that reference. 23 Q Why don't we put that to the side and 24 at a break we'll see if we can find that article</p>

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<p>1 and then we can take a look at it. Okay?</p> <p>2 A Uh-huh.</p> <p>3 Q Okay. Getting back, then, Doctor, to</p> <p>4 what we had marked as Exhibit 6, which is the</p> <p>5 Taher paper, fair to say you reviewed that paper</p> <p>6 after your report was submitted in this case?</p> <p>7 A Yes.</p> <p>8 Q Okay. And did you notice throughout</p> <p>9 Taher's paper he makes reference to a number of</p> <p>10 supplemental materials?</p> <p>11 A Not specifically.</p> <p>12 Q Are you in receipt from plaintiffs'</p> <p>13 counsel of those supplemental materials?</p> <p>14 A I'd have to -- you'd have to give me a</p> <p>15 specific example, and I would be able to answer</p> <p>16 you.</p> <p>17 Q So, throughout the paper, the authors</p> <p>18 make reference to a set of supplemental materials</p> <p>19 that support their opinions. Do you recall that?</p> <p>20 A I certainly recall the reference</p> <p>21 materials to support their opinion. Whether they</p> <p>22 were supplemental or otherwise, that doesn't</p> <p>23 stand out to me.</p> <p>24 Q Okay. And I'm not trying to be tricky.</p>	<p>1 A And I have those on the -- available</p> <p>2 electronically.</p> <p>3 Q Okay. Were you provided with completed</p> <p>4 versions of all the plaintiff experts in the MDL</p> <p>5 proceeding?</p> <p>6 A I can't speak to whether it was all,</p> <p>7 but I have been provided with several.</p> <p>8 Q Will you list for me the expert reports</p> <p>9 you've been provided with?</p> <p>10 A Sure.</p> <p>11 Q Thank you.</p> <p>12 A There are four on -- on this drive,</p> <p>13 three -- I'm sorry. Two. Crowley and Longo.</p> <p>14 Q Two reports from Dr. Crowley and two</p> <p>15 reports from Dr. Longo?</p> <p>16 MS. O'DELL:</p> <p>17 I don't think that's what he said.</p> <p>18 A No. I think there are two, two expert</p> <p>19 reports, one from Dr. Crowley and one from</p> <p>20 Dr. Longo.</p> <p>21 MS. BROWN:</p> <p>22 Q Okay. And the date of the Crowley</p> <p>23 report, please?</p> <p>24 A The -- according to the file, the</p>
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<p>1 I just want to know if you have those materials,</p> <p>2 and, if so, I'm gonna request production of them.</p> <p>3 A No. I -- I -- I don't believe that I</p> <p>4 have the full list of reference -- of literature</p> <p>5 cited from that -- from this paper --</p> <p>6 Q Okay.</p> <p>7 A -- now --</p> <p>8 Q Now, Taher --</p> <p>9 A -- but I'd have to check.</p> <p>10 Q Sorry.</p> <p>11 The Taher paper did not inform your --</p> <p>12 the opinions contained in your report dated</p> <p>13 November of 2018; correct?</p> <p>14 A Correct, as written.</p> <p>15 Q Okay. Are there any additional</p> <p>16 documents that either you or your counsel have</p> <p>17 brought with you here today in response to</p> <p>18 Exhibit 1, the Notice of Deposition?</p> <p>19 A So I'm not sure how to answer that</p> <p>20 accurately, but I would say there's a -- I've</p> <p>21 been provided with -- since the completion of my</p> <p>22 report, I've been provided with reports from</p> <p>23 other experts in the -- in the case.</p> <p>24 Q Okay.</p>	<p>1 date -- the modified date is November 28, 2018.</p> <p>2 Q And --</p> <p>3 A Whether that was the written date, I --</p> <p>4 I don't know.</p> <p>5 Q And the Longo report, do you know the</p> <p>6 date of that?</p> <p>7 A It is listed as August 2nd, 2017, in</p> <p>8 the title. And then there's a -- sorry. There's</p> <p>9 a second Longo report, 2018, which has a</p> <p>10 November 28, 2018, date. So my -- my apologies.</p> <p>11 To correct, there are two expert reports from</p> <p>12 Dr. Longo.</p> <p>13 Q Got it.</p> <p>14 MS. O'DELL:</p> <p>15 So when you were talking about --</p> <p>16 MS. BROWN:</p> <p>17 Counsel, no. Huh-uh. No. We -- I'm</p> <p>18 gonna ask questions, and he's gonna answer. We</p> <p>19 are not going to have you testify. You are not</p> <p>20 to testify about the expert reports.</p> <p>21 MS. O'DELL:</p> <p>22 I'm not gonna --</p> <p>23 You asked him what the date of the</p> <p>24 report was.</p>

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<p style="text-align: right;">Page 42</p> <p>1 MS. BROWN: 2 He -- then he will answer, counsel. 3 You can't testify. 4 MS. O'DELL: 5 He gave you the date of the file -- the 6 file date -- 7 MS. BROWN: 8 That's fine. 9 MS. O'DELL: 10 -- not the date -- 11 MS. BROWN: 12 On redirect, you are welcome to clean 13 up whatever you need to. But we're not gonna 14 have your testimony on the record about dates of 15 expert reports. 16 A So, looking at the report itself, the 17 date of the Longo report is November 14th, 2018. 18 MS. BROWN: 19 Q And were you provided -- 20 A The -- would you like the date of the 21 earlier report? 22 Q That would be terrific. 23 A It's August 2nd, 2017. 24 Q Great.</p>	<p style="text-align: right;">Page 44</p> <p>1 MS. BROWN: 2 Q How did you receive them? Was it email 3 or hard copy? 4 A Neither. They were made available 5 through a shared storage. 6 Q And would you have received an email 7 alerting you to their existence on a shared file? 8 MS. O'DELL: 9 Dr. Levy, communications between 10 counsel are -- are subject to the work product 11 privilege. 12 So to the degree you're asking him to 13 convey what was in a communication, then I'll 14 object to that and instruct you not to discuss 15 communications between counsel. 16 MS. BROWN: 17 Q Which the question does not ask for, 18 Doctor. 19 MS. O'DELL: 20 I believe it does. 21 MS. BROWN: 22 Q Here's what I want to know. Did you 23 rely on any other expert reports in forming your 24 opinions in this case?</p>
<p style="text-align: right;">Page 43</p> <p>1 Were you provided the two Longo reports 2 and the Dr. Crowley report by plaintiffs' 3 counsel? 4 A Yes. 5 Q Do you recall when? 6 A Not specifically. It was, obviously, 7 by their date, sometime after their completion. 8 So the Crowley report and the later 2018 Longo 9 report were sometime in November or December 10 2018. 11 There's -- I've also had an opportunity 12 to review a number of -- several other expert 13 reports which are not with me today. 14 Q Do you have a listing of the additional 15 expert reports you were provided with? 16 A I'd have to -- I could certainly -- I'd 17 have to provide it. I don't, off the top of my 18 head, recall all of them. There was probably 19 approximately a dozen. 20 Q Were all of the plaintiff expert 21 reports sent to you at once? 22 MS. O'DELL: 23 Object to the form. 24 A I'm not -- I'm not certain.</p>	<p style="text-align: right;">Page 45</p> <p>1 A To -- to my -- the content of my 2 report, no. 3 Q Did you receive the Crowley and two 4 Longo reports after you had already completed 5 your report in this case? 6 MS. O'DELL: 7 Object to the form. 8 A No. There was -- if I recall -- and 9 the -- at least the earlier Longo report -- and 10 I'd have to review the specifics -- at least the 11 earlier Longo report was reviewed and was 12 included in the content in the report. 13 And I would have to -- since the later 14 Longo report and then the final version of this 15 report were quite close together, I don't recall 16 if they overlapped or not. I'd have to review 17 the -- which references I used in here, which 18 will just take a moment. 19 So, yes, the -- I did include both 20 Longo reports. 21 Q The second Longo report was finalized 22 two days prior to your report. Is that right? 23 A Finalized, yes. 24 Q Did you see a draft of Longo's 2018</p>

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<p style="text-align: right;">Page 46</p> <p>1 report?</p> <p>2 A Yes. And the --</p> <p>3 Q And did you --</p> <p>4 A And as to when I saw the draft, I</p> <p>5 believe it was -- and it was sometime in the fall</p> <p>6 and/or when reports were being revised and</p> <p>7 expanded as more literature became available.</p> <p>8 Q Prior to Longo finalizing and signing</p> <p>9 his expert report in the MDL, you had access to a</p> <p>10 draft of that report; is that right?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A I can't speak to -- to that accurately.</p> <p>14 MS. BROWN:</p> <p>15 Q I thought you just testified you saw a</p> <p>16 version of the Longo 2018 report that was not</p> <p>17 final. Is that correct?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I'd have to -- I'd have to review</p> <p>21 my -- the -- the literature that I used for the</p> <p>22 report to accurately answer your question.</p> <p>23 MS. BROWN:</p> <p>24 Q Well, your report doesn't say a draft,</p>	<p style="text-align: right;">Page 48</p> <p>1 Q Did you type the expert report that</p> <p>2 we've marked as Exhibit 2 yourself?</p> <p>3 A I did.</p> <p>4 Q Did you write all contents of Exhibit 2</p> <p>5 yourself?</p> <p>6 A I did.</p> <p>7 Q Were there parts of your report that</p> <p>8 you lifted from other published articles?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A Could you describe "lifted"?</p> <p>12 MS. BROWN:</p> <p>13 Q Did you take the words of other authors</p> <p>14 and put them in your expert report as Exhibit 2?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A No. My -- my -- so my report is a</p> <p>18 review of the available literature at the time</p> <p>19 that the report was being developed. So, as</p> <p>20 such, it describes that -- that literature.</p> <p>21 As far as did I specifically copy words</p> <p>22 from other reports, no.</p> <p>23 MS. BROWN:</p> <p>24 Q Did you work with another plaintiff</p>
<p style="text-align: right;">Page 47</p> <p>1 and I'm wondering if you ever saw a non-finalized</p> <p>2 copy of the Longo report.</p> <p>3 A I didn't have an opportunity to compare</p> <p>4 the finalized Longo report to a -- what may be a</p> <p>5 draft or not to accurately answer your question</p> <p>6 if I saw a draft that was substantially different</p> <p>7 than what's referenced as the final.</p> <p>8 Q There were two days between Longo</p> <p>9 serving his report and you serving your report.</p> <p>10 Does that help orient you as to whether you saw a</p> <p>11 draft or you saw the final version?</p> <p>12 A Certainly possible I saw the final</p> <p>13 version.</p> <p>14 Q How many hours did you spend on your</p> <p>15 report in this case, Doctor?</p> <p>16 A The initial draft of the report? The</p> <p>17 initial writing of the report?</p> <p>18 Q In total, how many hours did you spend</p> <p>19 writing your report?</p> <p>20 A It was 20 hours initially, and then it</p> <p>21 would be -- it would be difficult to provide an</p> <p>22 accurate answer for the rest of that. I would</p> <p>23 say an additional few hours that I counted as</p> <p>24 revision.</p>	<p style="text-align: right;">Page 49</p> <p>1 expert on the report that we've marked as</p> <p>2 Exhibit 2?</p> <p>3 A I did not.</p> <p>4 Q Do you know who Dr. Zelikoff is?</p> <p>5 A The name's not familiar to me.</p> <p>6 Q Did you review a draft of</p> <p>7 Dr. Zelikoff's report before submitting your own?</p> <p>8 A I did not.</p> <p>9 Q Do you think that --</p> <p>10 A Not that I'm aware of.</p> <p>11 Q Do you have any explanation as to why a</p> <p>12 paragraph in your report is the same as a</p> <p>13 paragraph in Dr. Zelikoff's report?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A I -- without knowing -- without seeing</p> <p>17 the paragraph in both reports would be -- I can't</p> <p>18 comment.</p> <p>19 MS. BROWN:</p> <p>20 Q Let's mark as Exhibit 8 the expert</p> <p>21 report of Dr. Judith Zelikoff, Ph.D.</p> <p>22 (DEPOSITION EXHIBIT NUMBER 8</p> <p>23 WAS MARKED FOR IDENTIFICATION.)</p> <p>24 MS. BROWN:</p>

13 (Pages 46 to 49)

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<p style="text-align: right;">Page 50</p> <p>1 Q Is this something you've seen --</p> <p>2 Oh, sorry. Can I --</p> <p>3 It's okay, actually. It will flag it</p> <p>4 for you?</p> <p>5 Is this a report that you've seen</p> <p>6 before, Doctor?</p> <p>7 A I'll have to see it before I answer.</p> <p>8 Q I'm handing you what we've marked as</p> <p>9 Exhibit 8, which is the expert report of</p> <p>10 Dr. Judith Zelikoff. Is this one of the reports</p> <p>11 that you reviewed prior -- you reviewed at all?</p> <p>12 A I would have -- I would actually have</p> <p>13 to review my -- the literature that I reviewed</p> <p>14 in -- the totality of the literature that I</p> <p>15 reviewed, which I could answer that after a</p> <p>16 break, if necessary. But I don't recall,</p> <p>17 specifically recall, this report under</p> <p>18 Dr. Zelikoff's name. But it is certainly</p> <p>19 possible that I may have seen...</p> <p>20 Q Let's look at page 5 of your report,</p> <p>21 Doctor.</p> <p>22 A Okay.</p> <p>23 Q And why don't you put that side by side</p> <p>24 with page 20 of Dr. Zelikoff's report. And the</p>	<p style="text-align: right;">Page 52</p> <p>1 A They are --</p> <p>2 Q The next sentence --</p> <p>3 A Just one moment, please. I'm just</p> <p>4 making sure. Your question was are they exactly</p> <p>5 the same, and I'm just confirming if they're</p> <p>6 exactly the same.</p> <p>7 So, yes, I agree they're exactly the</p> <p>8 same.</p> <p>9 Q You have reviewed them and satisfied</p> <p>10 yourself that that -- those two sentences are</p> <p>11 exactly the same; correct?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A There's a single sentence in each</p> <p>15 report that is exactly the same. But important</p> <p>16 to comment that this single sentence is a -- is a</p> <p>17 basic biological premise of cancer, and, so,</p> <p>18 there's no surprise that two expert witnesses</p> <p>19 offering opinions on the role of -- or the</p> <p>20 biological plausibility or mechanisms of</p> <p>21 development of cancer would introduce a</p> <p>22 fundamental premise in the same manner.</p> <p>23 MS. BROWN:</p> <p>24 Q No surprise that you experts would have</p>
<p style="text-align: right;">Page 51</p> <p>1 paragraph in Dr. Zelikoff's report that I want to</p> <p>2 direct you to is the first full paragraph on</p> <p>3 page 20 that begins "Genetic mutations."</p> <p>4 Do you see that?</p> <p>5 A I do.</p> <p>6 Q And the paragraph of your report I want</p> <p>7 to direct you to is the paragraph on page 5 that</p> <p>8 begins "Both inherited."</p> <p>9 Do you see that?</p> <p>10 A I do.</p> <p>11 Q Okay. The first sentence of that</p> <p>12 paragraph in your report reads, "Both inherited</p> <p>13 and acquired gene -- and acquired gene mutations</p> <p>14 work together to cause cancer."</p> <p>15 Do you see that?</p> <p>16 A I do.</p> <p>17 Q The third sentence of the paragraph I</p> <p>18 directed you to in Dr. Zelikoff's report is</p> <p>19 identical and reads, "Both inherited and acquired</p> <p>20 gene mutations work together to cause cancer."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q Those two sentences are exactly the</p> <p>24 same, are they not?</p>	<p style="text-align: right;">Page 53</p> <p>1 one sentence that's the same? Is that what</p> <p>2 you're saying?</p> <p>3 MS. O'DELL:</p> <p>4 Objection. That's not what he said.</p> <p>5 Misrepresents his testimony.</p> <p>6 A I'm saying that both would -- both</p> <p>7 reports detail a fundamental aspect as they</p> <p>8 would -- based on the current understanding of</p> <p>9 the -- that both inherited and acquired gene</p> <p>10 mutations work in concert to cause cancer.</p> <p>11 MS. BROWN:</p> <p>12 Q Look at the next sentence on page 20 of</p> <p>13 Dr. Zelikoff's report. It reads as follows:</p> <p>14 "Even if one has inherited a genetic mutation</p> <p>15 that predisposes one to cancer," comma, "that</p> <p>16 doesn't mean he or she is certain to get cancer."</p> <p>17 Did I read that correctly?</p> <p>18 A You did.</p> <p>19 Q And let's go back to page 5 of your</p> <p>20 report. Skip ahead, if you would -- one, two,</p> <p>21 three -- four sentences to where you were and</p> <p>22 find the sentence that begins "Even."</p> <p>23 Are you with me?</p> <p>24 A I am.</p>

14 (Pages 50 to 53)

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<p style="text-align: right;">Page 54</p> <p>1 Q And your report at page 5 reads, "Even 2 if one has inherited a genetic mutation that 3 predisposes one to cancer," comma, "that doesn't 4 mean he or she is certain to get cancer." 5 Did I read that correctly? 6 A You did. 7 Q That's the exact same sentence we just 8 read in Dr. Zelikoff's report; correct? 9 A It is. 10 Q So now we have two sentences that are 11 exactly the same in your report and 12 Dr. Zelikoff's report. Correct? 13 MS. O'DELL: 14 Object to the form. 15 A You have two sentences that are written 16 the same but certainly not in precisely the same 17 context or organization in the total report. 18 MS. BROWN: 19 Q We have two sentences that are 20 word-for-word identical in two of the plaintiffs' 21 expert reports in this litigation. Is that fair? 22 MS. O'DELL: 23 Objection. Asked and answered. 24 A So reading your earlier question, you</p>	<p style="text-align: right;">Page 56</p> <p>1 identical to your report; correct? 2 A We have. 3 Q Do you have any explanation for why 4 that would be? 5 A I do. 6 Q What's that? 7 A That these -- each of these sentences 8 are describing basic introductory information 9 around the relationship between cancer and 10 genetic mutation. 11 Q And each of you described it with the 12 exact same words? 13 A Apparently so. 14 Q Let's keep going. 15 Page 20 of Dr. Zelikoff's report, 16 picking up where we left off, Dr. Zelikoff 17 writes: "The inherited gene mutation could 18 instead make one more likely to develop cancer 19 when exposed to certain cancer-causing 20 substances." 21 Do you see that? 22 A I do. 23 Q And let's go back to where we were in 24 your report, on page 5. "The inherited gene</p>
<p style="text-align: right;">Page 55</p> <p>1 asked, "Is that the same exact sentence we just 2 read in Dr. Zelikoff's report; correct?" And my 3 answer was "It is." And it remains the same. 4 Q Let's keep going. 5 Next sentence, at page 20 in 6 Dr. Zelikoff's report, states as follows: 7 "Rather," comma, "one or more additional gene 8 mutations may be needed to cause cancer." 9 Did I read that correctly? 10 A You did. 11 Q Let's go back to page 4 -- excuse me -- 12 page 5 of your report where we just were. And 13 you write: "Rather," comma, "one or more 14 additional gene mutations may be needed to cause 15 cancer." Correct? 16 A Correct. 17 Q That is the identical sentence from 18 Dr. Zelikoff's report. Correct? 19 A Starting with "Rather, one or more 20 additional gene mutations may be needed to cause 21 cancer." 22 Yes, correct. 23 Q So we now have identified three 24 sentences in Dr. Zelikoff's report that are</p>	<p style="text-align: right;">Page 57</p> <p>1 mutation could instead make one more likely to 2 develop cancer when exposed to a certain 3 cancer-causing substance." 4 Do you see that? 5 A I do. 6 Q And other than the tense in that last 7 sentence, they, too, are identical. Correct? 8 A So they're -- they're certainly similar 9 sentences, but that -- I believe the tense is an 10 important difference between them. 11 Again, as I stated, that these are 12 introductory and fundamental perspectives on 13 cancer and that, in this case, two expert 14 witnesses have summarized those things in a 15 similar fashion. 16 Q It doesn't strike you as odd that four 17 sentences are identical from two expert reports? 18 MS. O'DELL: 19 Object to the form. 20 A Four sentences are not identical. 21 MS. BROWN: 22 Q There's one small change in a tense. 23 That's it. Right, Doctor? 24 MS. O'DELL:</p>

15 (Pages 54 to 57)

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<p style="text-align: right;">Page 58</p> <p>1 Object to the form.</p> <p>2 A There -- there are -- there are three</p> <p>3 sentences which are, when considered</p> <p>4 individually, they are the same words. When you</p> <p>5 consider the -- now the group of those four</p> <p>6 sentences together between the two reports, they</p> <p>7 are clearly different organization with</p> <p>8 significantly more information between those</p> <p>9 identical sentences in one or the other.</p> <p>10 So the suggestion that they were -- one</p> <p>11 report was copied into the other, I would say it</p> <p>12 is equally interesting that they are more</p> <p>13 different than they are alike, other than the</p> <p>14 wording of three sentences.</p> <p>15 MS. BROWN:</p> <p>16 Q Did someone other than you write the</p> <p>17 sentences we've just been looking at in your</p> <p>18 report?</p> <p>19 A No.</p> <p>20 Q Did you consult the Mayo Clinic's</p> <p>21 website in connection with writing your report?</p> <p>22 A I don't believe so.</p> <p>23 Q Do you consider the Mayo Clinic's</p> <p>24 website to be authoritative -- an authoritative</p>	<p style="text-align: right;">Page 60</p> <p>1 Q -- next to your report, which remains</p> <p>2 Exhibit 2. And I will direct you to the second</p> <p>3 page of the Mayo Clinic printout, the section</p> <p>4 titled "Causes."</p> <p>5 Are you with me?</p> <p>6 A Second page.</p> <p>7 Q Double-sided. Flip it over.</p> <p>8 A Yes.</p> <p>9 Q Okay. And I'll direct you to page 3 of</p> <p>10 your report entitled "The Role of Gene Mutations</p> <p>11 in the Development of Cancer."</p> <p>12 A Uh-huh.</p> <p>13 Q Starting with Exhibit 9, the Mayo</p> <p>14 Clinic website, under a section entitled</p> <p>15 "Causes," the Mayo Clinic writes, "Cancer is</p> <p>16 caused by changes" -- parentheses --</p> <p>17 "(mutations) to the DNA within cells."</p> <p>18 Do you see that?</p> <p>19 A I do.</p> <p>20 Q And, looking at page 3 of your report,</p> <p>21 Doctor, that same sentence or sentence fragment</p> <p>22 appears in the first sentence: "Cancer is caused</p> <p>23 by changes" -- parentheses -- "(mutations) to the</p> <p>24 DNA within cells."</p>
<p style="text-align: right;">Page 59</p> <p>1 source, in your view?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A I have no basis for that opinion. I --</p> <p>5 I haven't reviewed the Mayo Clinic website to</p> <p>6 determine that.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 9</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q Handing you, Doctor, what we've marked</p> <p>11 as Exhibit 9 to your deposition, which is a</p> <p>12 printout from the Mayo Clinic website entitled</p> <p>13 "Cancer."</p> <p>14 A Uh-huh.</p> <p>15 Q I'll hand it to you. And let me know</p> <p>16 if this is something that you've ever seen</p> <p>17 before.</p> <p>18 A Not that I recall.</p> <p>19 Q Did you take any language from the Mayo</p> <p>20 Clinic website to use in your report?</p> <p>21 A No.</p> <p>22 Q Let's take a -- I want you to put the</p> <p>23 Mayo Clinic, which we've marked as Exhibit 9 --</p> <p>24 A Uh-huh.</p>	<p style="text-align: right;">Page 61</p> <p>1 Correct?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A Say your question again. Are you</p> <p>5 asking --</p> <p>6 MS. BROWN:</p> <p>7 Q It's the same; right, Doctor?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A There are eight words or ten words that</p> <p>11 are the same in this first sentence, again, both</p> <p>12 describing some of the fundamental premise of</p> <p>13 cancer and its -- in its description.</p> <p>14 MS. BROWN:</p> <p>15 Q Let's go to the second sentence in the</p> <p>16 Mayo Clinic website, which reads, "The DNA inside</p> <p>17 a cell is packaged into a large number of</p> <p>18 individual genes, each of which contains a set of</p> <p>19 instructions telling the cell what functions to</p> <p>20 perform," comma, "as well as how to grow and</p> <p>21 divide."</p> <p>22 Do you see that?</p> <p>23 A I do.</p> <p>24 Q And a nearly identical version of that</p>

16 (Pages 58 to 61)

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<p style="text-align: right;">Page 62</p> <p>1 sentence appears in your report at page 3 where</p> <p>2 you state, "The DNA that makes up our genetic</p> <p>3 code is organized into a large number of</p> <p>4 individual genes, each of which contains a</p> <p>5 specific subset of instructions telling the cell</p> <p>6 what functions to perform," comma, "as well as</p> <p>7 how to grow and divide."</p> <p>8 Do you see that?</p> <p>9 A I do.</p> <p>10 Q Do you notice that nearly all the words</p> <p>11 are the same as the Mayo Clinic's?</p> <p>12 MS. O'DELL:</p> <p>13 Objection to form.</p> <p>14 A I, again -- we -- we have another</p> <p>15 example of similar language describing</p> <p>16 introductory and fundamental aspects surrounding</p> <p>17 the basics of cancer biology.</p> <p>18 MS. BROWN:</p> <p>19 Q Back to the Mayo Clinic next sentence.</p> <p>20 Quote: "Errors in the instructions can cause the</p> <p>21 cell to stop its normal function and may allow a</p> <p>22 cell to become cancerous."</p> <p>23 Do you see that?</p> <p>24 A I do.</p>	<p style="text-align: right;">Page 64</p> <p>1 subparagraph titled "Loss of DNA Repair."</p> <p>2 Are you with me?</p> <p>3 A Yes.</p> <p>4 Q I'm gonna read you two sentences from</p> <p>5 the Mayo Clinic. Tell me if I read them</p> <p>6 correctly.</p> <p>7 "DNA repair genes look for errors in a</p> <p>8 cell's DNA and make corrections. A mutation in a</p> <p>9 DNA repair gene may mean that other errors aren't</p> <p>10 corrected, leading cells to become cancerous."</p> <p>11 Do you see those two sentences, Doctor?</p> <p>12 A I do.</p> <p>13 Q Those are two sentences written by the</p> <p>14 folks who produce the Mayo Clinic's website;</p> <p>15 correct?</p> <p>16 A I -- I have no knowledge of who wrote</p> <p>17 that.</p> <p>18 Q The same two sentences appear in your</p> <p>19 report on page 4. Quote: "DNA repair genes look</p> <p>20 for errors in a cell's DNA and make corrections.</p> <p>21 A mutation in a DNA repair gene may mean that</p> <p>22 other errors aren't corrected, leading cells to</p> <p>23 become cancerous."</p> <p>24 Do you see that?</p>
<p style="text-align: right;">Page 63</p> <p>1 Q Back to your report at page 3. An</p> <p>2 identical sentence: "Errors in the instruction</p> <p>3 can cause the cell to stop its normal function</p> <p>4 and may allow a cell to become cancerous."</p> <p>5 Do you see that?</p> <p>6 A I do.</p> <p>7 Q Does that strike you as strange?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A Strange in what way?</p> <p>11 MS. BROWN:</p> <p>12 Q That your expert report in this</p> <p>13 litigation contains identical sentences to the</p> <p>14 Mayo Clinic's website.</p> <p>15 MS. O'DELL:</p> <p>16 Objection. Misstates the report.</p> <p>17 A I -- I don't find it surprising in the</p> <p>18 least.</p> <p>19 MS. BROWN:</p> <p>20 Q Let's turn to page 4 of your report,</p> <p>21 please. And I'll direct you to the final bullet</p> <p>22 on the same page of the Mayo Clinic website you</p> <p>23 were just looking at. The section of your report</p> <p>24 on page 4 I'd like to direct you to is the</p>	<p style="text-align: right;">Page 65</p> <p>1 A I do.</p> <p>2 Q Those two sentences are identical in</p> <p>3 the Mayo Clinic's website and your report. True?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A Again, we have fund- -- basic</p> <p>7 information that provides an introductory</p> <p>8 description of the basics of cancer which is used</p> <p>9 as -- as an inform- -- informatory foundation for</p> <p>10 latter opinions in the report but is not germane</p> <p>11 to the -- to the opinion in my report.</p> <p>12 And, again, as stated before, that</p> <p>13 succinct fundamental information regarding cancer</p> <p>14 biology in two sources that state things</p> <p>15 succinctly and clearly in layman's language</p> <p>16 are -- are similar or even identical, again, does</p> <p>17 not surprise me.</p> <p>18 MS. BROWN:</p> <p>19 Q We read at least four sentences that</p> <p>20 are identical to the Mayo Clinic. Would you</p> <p>21 agree?</p> <p>22 MS. O'DELL:</p> <p>23 Objection to form. The sentences are</p> <p>24 not identical.</p>

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<p style="text-align: right;">Page 66</p> <p>1 MS. BROWN: 2 Counsel, form. 3 A There are some similar -- there are 4 some similarly stated sentences that 5 you're -- that you've taken out of context in 6 both cases to find them identical. So I -- I 7 agree that they're identical, but, again, 8 don't -- don't necessarily am surprised since I 9 have no knowledge of where the information from 10 the Mayo website was taken from. 11 MS. BROWN: 12 Q You agree a number of sentences in your 13 report are identical to a number of sentences on 14 the Mayo Clinic's website. True? 15 MS. O'DELL: 16 Object to the form. 17 A No. I agree that they're -- I don't 18 agree. There are specific wordings that are the 19 same. 20 MS. BROWN: 21 Q Doctor, do you not agree that a number 22 of the sentences we just read are identical to a 23 number of sentences that appear on the Mayo 24 Clinic's website?</p>	<p style="text-align: right;">Page 68</p> <p>1 from our conversation to comment on those. 2 MS. BROWN: 3 Q You have it right in front of you. We 4 just looked at them. 5 A We did. 6 Q Right? 7 A Yes. 8 Q You recall reading a number of 9 sentences in the Mayo Clinic website that match 10 word for word a number of sentences in your 11 report. True? 12 MS. O'DELL: 13 Object to the form. 14 A We've -- we've read information that 15 is -- that is similar between the two documents. 16 And, as answered, given the, again, basic 17 fundamental introduction in lay language for 18 these concepts, it is no surprise that it's the 19 same. 20 MS. BROWN: 21 Q You're not surprised to find identical 22 sentences in your report and Dr. Zelickoff's 23 report? 24 A I'm not surprised.</p>
<p style="text-align: right;">Page 67</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A I think we've -- we've specifically 4 gone over those individually and answered those 5 questions. 6 MS. BROWN: 7 Q And you'll agree the sentences are 8 identical? 9 MS. O'DELL: 10 Object to the form. 11 A Again, I -- I've answered -- I've 12 answered those when we went through them 13 individually. 14 MS. BROWN: 15 Q Well, I want you to answer my question 16 now. 17 You'll agree we've looked at a number 18 of sentences that are identical in your report to 19 the information on the Mayo Clinic's website; 20 correct? 21 MS. O'DELL: 22 Object to the form. Misstates his 23 testimony. 24 A I'd have to go back to the transcript</p>	<p style="text-align: right;">Page 69</p> <p>1 MS. O'DELL: 2 Object to the form. 3 MS. BROWN: 4 Q You are not surprised to find identical 5 sentences in your report and the Mayo Clinic? 6 MS. O'DELL: 7 Objection to form. Asked and answered. 8 A No. I -- I've answered that. 9 MS. BROWN: 10 Q You need to answer it again. 11 Are you -- 12 A I'm not surprised. 13 Q -- surprised? 14 Did you consult Wikipedia in writing 15 your expert report? 16 A I don't recall. 17 Q Do you think it's possible you might 18 have looked at Wikipedia when writing your expert 19 report in this litigation? 20 A I've -- I've looked -- I've looked at a 21 large number of sources in published literature 22 and others. 23 Q Did one of those sources include 24 Wikipedia?</p>

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<p>1 A I don't recall.</p> <p>2 Q Do you consider Wikipedia to be a</p> <p>3 scientifically reliable source?</p> <p>4 A What do you mean by scientifically</p> <p>5 reliable.</p> <p>6 Q Do you understand the concept of</p> <p>7 scientific reliability when answering a</p> <p>8 scientific question?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A Again, you'd have to -- that's -- you'd</p> <p>12 have to explain your -- what scientific</p> <p>13 reliability means in the context of your</p> <p>14 question.</p> <p>15 MS. BROWN:</p> <p>16 Q What does it mean to you?</p> <p>17 A Scientific reliability? In general</p> <p>18 terms, it would mean information that comes from</p> <p>19 a peer-reviewed source.</p> <p>20 Q And Wikipedia is not peer-reviewed;</p> <p>21 correct?</p> <p>22 A Wikipedia generally reso- -- uses</p> <p>23 a -- is a summary of commonly -- at least in</p> <p>24 scientific terms, a number of peer-reviewed</p>	<p>1 And we'll mark a Wikipedia page as</p> <p>2 Exhibit 10.</p> <p>3 (DEPOSITION EXHIBIT NUMBER 10</p> <p>4 WAS MARKED FOR IDENTIFICATION.)</p> <p>5 MS. BROWN:</p> <p>6 Q I would like to direct you, Dr. Levy,</p> <p>7 to the first full paragraph in your expert report</p> <p>8 at page 7.</p> <p>9 A Uh-huh.</p> <p>10 Q Do you see that?</p> <p>11 A I do.</p> <p>12 Q And I want to direct your attention to</p> <p>13 the sentence in the middle of that paragraph that</p> <p>14 begins "BRCA1 combined."</p> <p>15 Do you see that?</p> <p>16 A Yes.</p> <p>17 MS. BROWN:</p> <p>18 Q And I want to, side by side with</p> <p>19 Wikipedia, direct your attention to the third</p> <p>20 full paragraph that begins, as well, "BRCA1</p> <p>21 combined."</p> <p>22 You with me?</p> <p>23 A I am.</p> <p>24 Q Wikipedia writes, "BRCA1 combines with</p>
Page 71	Page 73
<p>1 sources, but it is --</p> <p>2 So from a true peer-review perspective,</p> <p>3 Wikipedia actually is peer-reviewed in the sense</p> <p>4 that anyone can contribute and edit the</p> <p>5 information in Wikipedia.</p> <p>6 Q Including our kids; right?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form.</p> <p>9 A Possible.</p> <p>10 MS. BROWN:</p> <p>11 Q Anyone in the world could edit a</p> <p>12 Wikipedia page. True?</p> <p>13 A I believe so.</p> <p>14 Q Is it your testimony, Doctor, that</p> <p>15 information from Wikipedia is a reliable resource</p> <p>16 when answering a scientific question?</p> <p>17 A No, that is not my testimony. That is</p> <p>18 not my testimony, no.</p> <p>19 Q Do you -- do you think you used</p> <p>20 Wikipedia here in writing your report?</p> <p>21 A Again, I -- I -- I don't recall using</p> <p>22 Wikipedia specifically.</p> <p>23 Q Okay. Let's take a look at your report</p> <p>24 at page 7, Doctor.</p>	<p>1 other tumor suppressors, DNA damage sensors, and</p> <p>2 single transducers to form a large multi-subunit</p> <p>3 protein complex known as BRCA1-associated genome</p> <p>4 surveillance complex" -- parens --</p> <p>5 "BAC-" -- excuse me -- "(BASC)," end parens.</p> <p>6 Do you see that?</p> <p>7 A I do.</p> <p>8 Q Turning to your report, page 7, you</p> <p>9 write, "BRCA1 combines with other tumor</p> <p>10 suppressors," comma, "DNA damage sensors, and</p> <p>11 signal transducers to form a large multi-subunit</p> <p>12 protein complex known as the BRCA1-associated</p> <p>13 genome surveillance complex" -- parens --</p> <p>14 (BASC)."</p> <p>15 Correct?</p> <p>16 A That is correct.</p> <p>17 Q Those two sentences, Doctor, are</p> <p>18 identical.</p> <p>19 A It appears so, yes.</p> <p>20 Q Okay.</p> <p>21 A Except for a -- the reference included</p> <p>22 on the Wikipedia page is not included in my</p> <p>23 report.</p> <p>24 Q Wikipedia has cited a reference, and</p>

19 (Pages 70 to 73)

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<p style="text-align: right;">Page 74</p> <p>1 your sentence stands without a reference. Is</p> <p>2 that right?</p> <p>3 A That's right.</p> <p>4 Q Other than the footnote, the two</p> <p>5 sentences we just read are identical. True?</p> <p>6 A Both sentences state the same fact in</p> <p>7 the same way. So, similar to our earlier</p> <p>8 discussions, we've now seen a large collection of</p> <p>9 fundamental factual information with -- with</p> <p>10 accurate information from now a number of sources</p> <p>11 that are stated in similar ways through</p> <p>12 Wikipedia, other expert reports, and websites all</p> <p>13 about the fundamentals of cancer.</p> <p>14 Q The two sentences we just read, Doctor,</p> <p>15 are identical. Correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A We read one sentence in Wikipedia.</p> <p>19 MS. BROWN:</p> <p>20 Q And it is identical. True?</p> <p>21 A Yes. The wording is the same. With,</p> <p>22 of course, Wikipedia, as you already stated,</p> <p>23 being editable by anybody and can pull that</p> <p>24 content from anywhere, and it's the -- I'd have</p>	<p style="text-align: right;">Page 76</p> <p>1 Q I'm sorry. What did we mark the</p> <p>2 Coussens as? 12?</p> <p>3 A Twelve.</p> <p>4 Q That should have been 11.</p> <p>5 We have marked the Coussens' article</p> <p>6 now correctly as Exhibit 11, and I'll direct you</p> <p>7 to the last two sentences of the first full</p> <p>8 paragraph. Put that, if you would, Doctor, side</p> <p>9 by side with your report at page 9, sentence that</p> <p>10 begins "in contrast," both sentences that begin</p> <p>11 "in contrast."</p> <p>12 Are you with me?</p> <p>13 A I am.</p> <p>14 Q All right. So, in this published</p> <p>15 article, Ms. or Dr. Coussens writes, "In</p> <p>16 contrast, proliferating cells that sustain</p> <p>17 DNA" --</p> <p>18 MS. O'DELL:</p> <p>19 Excuse me, Alli. Sorry. Tell me, are</p> <p>20 you in the second paragraph?</p> <p>21 MS. BROWN:</p> <p>22 I'm on the end of the first full</p> <p>23 paragraph.</p> <p>24 MS. O'DELL:</p>
<p style="text-align: right;">Page 75</p> <p>1 to review -- I'd have to look to see what</p> <p>2 reference 16 in Wikipedia is. But it's certainly</p> <p>3 possible that I and Wikipedia summarized the same</p> <p>4 information from the same source.</p> <p>5 Q Let's go to page 9 of your report. One</p> <p>6 of the articles that you relied on is an article</p> <p>7 by Lisa Coussens and Zena Werb. Do you recall</p> <p>8 that?</p> <p>9 A That does sound familiar, but I'll have</p> <p>10 to verify.</p> <p>11 Q Handing you what we've marked as</p> <p>12 Exhibit 12 [sic] to your report, the Coussens and</p> <p>13 Werb article.</p> <p>14 (DEPOSITION EXHIBIT NUMBER 11</p> <p>15 WAS MARKED FOR IDENTIFICATION.)</p> <p>16 A Yes, this is a -- this is a review.</p> <p>17 This is an insight review article, which, similar</p> <p>18 to my report, is likely consolidating information</p> <p>19 from the research knowledge.</p> <p>20 MS. BROWN:</p> <p>21 Q I'd like to direct you to the last two</p> <p>22 sentences of Exhibit 10, the Coussens' article,</p> <p>23 the last two sentences in the first paragraph.</p> <p>24 A Exhibit 10 or 12?</p>	<p style="text-align: right;">Page 77</p> <p>1 Sorry. I thought you were in the first</p> <p>2 full paragraph.</p> <p>3 MS. BROWN:</p> <p>4 Begins "In contrast."</p> <p>5 MS. O'DELL:</p> <p>6 Okay.</p> <p>7 MS. BROWN:</p> <p>8 And we have that side by side with</p> <p>9 Dr. Levy's report, page 9, the paragraph that</p> <p>10 also begins "In contrast."</p> <p>11 MS. O'DELL:</p> <p>12 Thank you.</p> <p>13 MS. BROWN:</p> <p>14 Q Dr. Coussens writes, "In contrast,</p> <p>15 proliferating cells that sustain DNA damage</p> <p>16 and/or mutagenic assault" -- parens -- "(for</p> <p>17 example, initiated cells), continue to</p> <p>18 proliferate in microenvironments rich in</p> <p>19 inflammatory cells and growth/survival factors</p> <p>20 that support their growth."</p> <p>21 Do you see that sentence?</p> <p>22 A I do.</p> <p>23 Q The next sentence reads, "In a sense,"</p> <p>24 comma, "tumors act as wounds that fail to heal."</p>

20 (Pages 74 to 77)

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<p>1 See that?</p> <p>2 A I do.</p> <p>3 Q Directing your attention to page 9 of</p> <p>4 your report, Doctor, you write, "In contrast,"</p> <p>5 comma, "proliferating cells that sustain DNA</p> <p>6 damage and/or mutagenic insult -- parens -- "(for</p> <p>7 example," comma, "initiated cells)," end paren,</p> <p>8 "continue to proliferate in microenvironments</p> <p>9 rich in inflammatory cells and growth/survival</p> <p>10 factors that support their growth," period. "In</p> <p>11 a sense, tumors act as wounds that fail to heal."</p> <p>12 Do you see that?</p> <p>13 A I do.</p> <p>14 Q Except for one word, Doctor, those two</p> <p>15 sentences, including the slashes and the</p> <p>16 parentheses, are identical. Correct?</p> <p>17 MS. O'DELL:</p> <p>18 Object to the form.</p> <p>19 A Those two sentences are similar.</p> <p>20 MS. BROWN:</p> <p>21 Q Except for one word, those two</p> <p>22 sentences are identical. True?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form. Asked and</p>	<p>1 Q My question, Doctor, was: Except for</p> <p>2 one word, the two sentences we just read from</p> <p>3 Coussens are identical to the two sentences in</p> <p>4 your report. Is that correct?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A So, I -- as -- as stated, the two</p> <p>8 sentences are similar.</p> <p>9 MS. BROWN:</p> <p>10 Q Except for one word, they are</p> <p>11 identical. Is that correct?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form. He's asked --</p> <p>14 you've asked the question. He's answered your</p> <p>15 question.</p> <p>16 A Again, the two sentences are similar.</p> <p>17 MS. BROWN:</p> <p>18 Q Do you understand "identical," what</p> <p>19 "identical" means?</p> <p>20 A Yes. Exactly the same.</p> <p>21 Q Okay. Except for one word, those two</p> <p>22 sentences are exactly the same in the Coussens</p> <p>23 article and your report. True?</p> <p>24 MS. O'DELL:</p>
Page 79	Page 81
<p>1 answered.</p> <p>2 A Yeah. I'd certainly appreciate the</p> <p>3 similarity between the -- between the two. But</p> <p>4 that's -- again, as we've been discussing now for</p> <p>5 an extensive amount of time, in the introductory</p> <p>6 review content of the report --</p> <p>7 In fact, I reference the Coussens and</p> <p>8 Werb paper, so certainly it's not a surprise that</p> <p>9 wording is similar between them and used similar</p> <p>10 language to describe, again, these factual</p> <p>11 aspects of fundamental cancer biology, including</p> <p>12 similar references.</p> <p>13 MS. O'DELL:</p> <p>14 Excuse me. My microphone is broken.</p> <p>15 VIDEOGRAPHER:</p> <p>16 It's still working. You're good. You</p> <p>17 can just lay it on the table and we'll fix it at</p> <p>18 a break.</p> <p>19 MS. O'DELL:</p> <p>20 And we've been going about an hour and</p> <p>21 13 minutes.</p> <p>22 MS. BROWN:</p> <p>23 I'm about to finish up this section.</p> <p>24 We'll take a break.</p>	<p>1 Object to the form. Asked and</p> <p>2 answered.</p> <p>3 A And we're -- we're saying the same</p> <p>4 thing in different ways, which is that the two</p> <p>5 sentences are similar, stating factual</p> <p>6 information about fundamental cancer biology and</p> <p>7 in two similar review articles.</p> <p>8 MS. BROWN:</p> <p>9 Q And the only difference is one word.</p> <p>10 Correct?</p> <p>11 A Two sentences are similar.</p> <p>12 Q My question was: The only difference</p> <p>13 is one word. True?</p> <p>14 A Let me review again to be sure that we</p> <p>15 would -- before answering.</p> <p>16 Taken out of context, those two</p> <p>17 sentences are similar.</p> <p>18 Q My question was, Doctor, the only</p> <p>19 difference is one word. Is that correct?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to the form. Asked and</p> <p>22 answered.</p> <p>23 A You know, I think we've -- we've</p> <p>24 answered this a number of times, that the two</p>

21 (Pages 78 to 81)

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<p>1 sentences are different in their context and in</p> <p>2 terms of paragraph, but they are similar in</p> <p>3 structure and similar in wording.</p> <p>4 But, as you stated, with the exception</p> <p>5 of the -- so they're not. So in a language</p> <p>6 perspective, they're not identical. They're</p> <p>7 similar.</p> <p>8 MS. BROWN:</p> <p>9 Let's take a break.</p> <p>10 VIDEOGRAPHER:</p> <p>11 Going off -- going off the record. The</p> <p>12 time is 10:15 a.m.</p> <p>13 (OFF THE RECORD.)</p> <p>14 VIDEOGRAPHER:</p> <p>15 We're back on the record. The time is</p> <p>16 10:25 a.m.</p> <p>17 MS. BROWN:</p> <p>18 Q Doctor, I am handing you what I have</p> <p>19 marked as Deposition Exhibit 12 and 13. These</p> <p>20 are additional documents your counsel identified</p> <p>21 for us this morning as something you have seen</p> <p>22 since your report.</p> <p>23 (DEPOSITION EXHIBITS 12 AND 13</p> <p>24 WERE MARKED FOR IDENTIFICATION.)</p>	<p>1 A I have.</p> <p>2 Q Have you seen the reviewer comments</p> <p>3 referenced in Exhibit 13?</p> <p>4 A I have not seen the reviewer comments.</p> <p>5 Q Okay. Exhibit 13 does not inform the</p> <p>6 opinions of your report dated November of 2018.</p> <p>7 True?</p> <p>8 A Exhibit 13, being the letter, that is</p> <p>9 correct. It does not.</p> <p>10 Q Okay. And what's Exhibit 12?</p> <p>11 A Exhibit 12 appears to be a preprint</p> <p>12 version of the previously mentioned paper,</p> <p>13 "Molecular Basis Supporting the Association of</p> <p>14 Talcum Powder Use With Increased Risk of Ovarian</p> <p>15 Cancer," with the first author, Nicole Fletcher,</p> <p>16 and Dr. Saed is listed as the senior or</p> <p>17 corresponding author.</p> <p>18 Q Did the lawyers provide you with this</p> <p>19 manuscript, Doctor?</p> <p>20 A Yes, in a -- but that's -- yes, they</p> <p>21 did.</p> <p>22 Q Do you recall when you were provided</p> <p>23 with a copy of the manuscript by the plaintiffs'</p> <p>24 lawyers?</p>
Page 83	Page 85
<p>1 MS. BROWN:</p> <p>2 Q Would you tell us what those two</p> <p>3 exhibits are, please.</p> <p>4 A Exhibit -- Exhibit 13 is a printed copy</p> <p>5 of an email dated December 26th informing</p> <p>6 Dr. Saed that a manuscript --</p> <p>7 Is it helpful to identify the</p> <p>8 manuscript?</p> <p>9 -- titled "Molecular Basis Supporting</p> <p>10 the Association of Talcum Powder Use With</p> <p>11 Increased Risk of Ovarian Cancer," submitted to</p> <p>12 Reproductive Sciences, has been reviewed. The</p> <p>13 comments were included in the letter.</p> <p>14 Q Have you seen --</p> <p>15 A And I'm just reading the --</p> <p>16 Q Sure.</p> <p>17 A It -- it appears that the -- so,</p> <p>18 summarizing the letter, the manuscript has been</p> <p>19 reviewed, the comments from the reviewers were</p> <p>20 provided back, and the journal has informed</p> <p>21 Dr. Saed that they'll accept a revised document</p> <p>22 for potential publication.</p> <p>23 Q Have you seen Exhibit 13 prior to this</p> <p>24 morning?</p>	<p>1 A It was sometime in December toward --</p> <p>2 late in the year. The exact date, I'd have to</p> <p>3 review when it came in. And I believe it was --</p> <p>4 and the version you have here is a more formal</p> <p>5 preprint version from the -- from Manuscript</p> <p>6 Central, whereas the version I received</p> <p>7 was a -- it appeared to be more of a submission</p> <p>8 version.</p> <p>9 So commenting whether it's</p> <p>10 exact -- precisely the same content, I -- I</p> <p>11 wouldn't be able to say.</p> <p>12 Q Fair to say, though, Doctor, since you</p> <p>13 received the manuscript in December of 2018, the</p> <p>14 contents of the manuscript did not inform the</p> <p>15 expert report that you wrote in November of 2018;</p> <p>16 correct?</p> <p>17 A Actually, I would say the -- the -- I</p> <p>18 would not agree, from the perspective of Dr. Saed</p> <p>19 has a number of similar studies, as well as a</p> <p>20 number of abstracts that I had the opportunity to</p> <p>21 review that did inform some of the opinions in</p> <p>22 the report. Those same information and data were</p> <p>23 included in this manuscript and expanded upon</p> <p>24 actually significantly.</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 So the basis of my opinion includes</p> <p>2 some of the information from this manuscript, but</p> <p>3 I -- but the report does not contain the totality</p> <p>4 of this.</p> <p>5 Q Right. Because the manuscript wasn't</p> <p>6 available to you until after you wrote your</p> <p>7 report. Right?</p> <p>8 A No, that's not the case. The -- the --</p> <p>9 the research, some of the research information</p> <p>10 from this study was available in abstract form,</p> <p>11 and -- and some -- I believe a preprint from</p> <p>12 Dr. Saed.</p> <p>13 So it was -- so it was available.</p> <p>14 Portions of it were available for the report.</p> <p>15 Q Other than the abstract, did you have</p> <p>16 access to an earlier version of what we've marked</p> <p>17 as Exhibit 12?</p> <p>18 A I can't accurately answer that without</p> <p>19 comparing them.</p> <p>20 Q Where do you have stored the earlier</p> <p>21 version that you're referring to?</p> <p>22 A Let's see if I -- what I have here.</p> <p>23 So, from Dr. Saed, I have a -- used a</p> <p>24 book chapter which describes some of his</p>	<p style="text-align: right;">Page 88</p> <p>1 Q Okay. And I'll ask if you'd be kind</p> <p>2 enough to do that at a break. Just let us know</p> <p>3 if you had access to something other than the</p> <p>4 abstract of Dr. Saed's 2018 report at the time</p> <p>5 you wrote your report. Fair enough?</p> <p>6 A I'll make a note.</p> <p>7 MS. O'DELL:</p> <p>8 Excuse me. Object to the form.</p> <p>9 Abstracts, not one.</p> <p>10 MS. BROWN:</p> <p>11 Q Dr. Levy, you are a Ph.D.; is that</p> <p>12 correct?</p> <p>13 A Correct.</p> <p>14 Q Okay. You are not an M.D.; correct?</p> <p>15 A That's correct.</p> <p>16 Q What's your Ph.D. in, sir?</p> <p>17 A Biochemistry and genetics.</p> <p>18 Q You're not an epidemiologist. Fair?</p> <p>19 A I am not.</p> <p>20 Q Okay. And the focus of your work at</p> <p>21 HudsonAlpha is on genome sequencing. Is that</p> <p>22 right?</p> <p>23 A No. The -- the -- genome sequencing is</p> <p>24 a tool that we apply in -- in the work of my</p>
<p style="text-align: right;">Page 87</p> <p>1 oxidative stress experiments that are also</p> <p>2 consistent with the information that's in the --</p> <p>3 in Exhibit 12, as well as some of his earlier</p> <p>4 review articles, and that's --</p> <p>5 Let me make sure I'm not missing</p> <p>6 anything from Fletcher, who's been...</p> <p>7 But, otherwise, the -- the experiments</p> <p>8 that were expanded upon in the formal manuscript</p> <p>9 were described in -- in abstract or, I should</p> <p>10 say, summarized form, meaning an abstract that</p> <p>11 included methods, results, and conclusions from</p> <p>12 Fletcher and colleagues in Dr. Saed's group.</p> <p>13 Q At the time you wrote your report, you</p> <p>14 had an abstract of the 2018 paper that we've</p> <p>15 marked as Exhibit 12; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form. He said plural.</p> <p>18 A Yes. I had two abstracts and then</p> <p>19 possibly --</p> <p>20 I'd have to review when I received this</p> <p>21 preprint versus the final version of my report to</p> <p>22 see if they overlapped, if they're -- if I had an</p> <p>23 opportunity to review this or not.</p> <p>24 MS. BROWN:</p>	<p style="text-align: right;">Page 89</p> <p>1 laboratory and in my responsibilities at</p> <p>2 HudsonAlpha.</p> <p>3 Q HudsonAlpha has a team known as the</p> <p>4 Breakthrough Breast and Ovarian Cancer Team. Is</p> <p>5 that right?</p> <p>6 A I'm not familiar with that name.</p> <p>7 Q Okay.</p> <p>8 A There is a -- a group of faculty who</p> <p>9 have some funding related to breast and ovarian</p> <p>10 cancer. It's -- it's certainly possible that</p> <p>11 name was used in -- in press for some title.</p> <p>12 Q Since you're not familiar with that</p> <p>13 team, fair to say you're not a member of the</p> <p>14 Breakthrough Breast and Ovarian Cancer Team?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A Again, I don't -- my involvement with</p> <p>18 breast and ovarian cancer at HudsonAlpha is</p> <p>19 specific to some projects. And whether or not I</p> <p>20 was named on that team, I -- I don't know.</p> <p>21 MS. BROWN:</p> <p>22 Q There are folks at HudsonAlpha,</p> <p>23 scientists and doctors at HudsonAlpha whose</p> <p>24 practice is devoted to studying ovarian cancer.</p>

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<p style="text-align: right;">Page 90</p> <p>1 Correct?</p> <p>2 A No, that's not correct.</p> <p>3 Q Your practice is not devoted to ovarian</p> <p>4 cancer; correct?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A No. My -- my practice is not devoted</p> <p>8 to ovarian cancer. And -- but that was</p> <p>9 irrelevant to what I was asked to do in</p> <p>10 this -- in this particular case for</p> <p>11 the -- regarding the content of my report.</p> <p>12 MS. BROWN:</p> <p>13 Q I think I saw you've published one</p> <p>14 article regarding ovarian cancer over the course</p> <p>15 of your career. Is that right?</p> <p>16 A That sounds correct.</p> <p>17 Q You have not given any presentations</p> <p>18 regarding ovarian cancer. Is that true?</p> <p>19 A I would say that's accurate.</p> <p>20 Q You have not received any government</p> <p>21 funding to study ovarian cancer. True?</p> <p>22 A I received government funding to study</p> <p>23 breast and ovarian cancer -- this was in 2002,</p> <p>24 from the Department of Defense -- and then,</p>	<p style="text-align: right;">Page 92</p> <p>1 dating back to my early Ph.D. work, and those</p> <p>2 include cancer. So certainly the subject of</p> <p>3 inflammatory response in -- both chronic and</p> <p>4 acute, in controlling cancer has been a subject</p> <p>5 of my research for some time and certainly</p> <p>6 bridged into ovarian cancer as well as other</p> <p>7 cancer types.</p> <p>8 MS. BROWN:</p> <p>9 Q You've never published on chronic</p> <p>10 inflammation as a potential mechanism by which</p> <p>11 talcum powder causes ovarian cancer. Correct?</p> <p>12 A Not specific to talcum powder, no.</p> <p>13 Q You have never given a presentation on</p> <p>14 chronic inflammation as a mechanism for causing</p> <p>15 ovarian cancer at all; right?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A I'm thinking through my --</p> <p>19 I don't recall a specific presentation</p> <p>20 with regards to talcum powder and its role in</p> <p>21 ovarian cancer. As far as my discussions or</p> <p>22 presentations around the role of inflammation in</p> <p>23 cancer, including ovarian, it -- it is -- it is</p> <p>24 possible, but I can't think of a specific</p>
<p style="text-align: right;">Page 91</p> <p>1 subsequent to that, participated in at least one</p> <p>2 review for the Department of Defense in reviewing</p> <p>3 ovarian cancer research grants. So that is --</p> <p>4 And then my membership in the</p> <p>5 Vanderbilt Cancer Center as well as the</p> <p>6 University of Alabama Birmingham Comprehensive</p> <p>7 Cancer Center certainly have been involved in a</p> <p>8 number of projects across a diversity of cancer</p> <p>9 types, including ovarian and breast cancer.</p> <p>10 Q Prior to being hired by the plaintiffs'</p> <p>11 lawyers in this litigation, you had not</p> <p>12 investigated the potential mechanisms by which</p> <p>13 talcum powder could cause ovarian cancer. Is</p> <p>14 that fair?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A Specific -- as in terms of a specific</p> <p>18 fundamental research project?</p> <p>19 MS. BROWN:</p> <p>20 Q At all.</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A So my research has included the role of</p> <p>24 inflammation and a number of biological processes</p>	<p style="text-align: right;">Page 93</p> <p>1 presentation.</p> <p>2 MS. BROWN:</p> <p>3 Q Okay. Since you've been hired by</p> <p>4 plaintiffs' lawyers, you have done some research</p> <p>5 into the potential role of inflammation and</p> <p>6 ovarian cancer. Is that right?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form.</p> <p>9 A Since -- since my -- what was requested</p> <p>10 of me from the plaintiffs' attorneys was to</p> <p>11 provide a review of the biological plausibility</p> <p>12 and a connection between talcum powder and</p> <p>13 inflammation and then discuss the relationship</p> <p>14 between inflammation and cancer.</p> <p>15 MS. BROWN:</p> <p>16 Q Okay. As I understand you, Dr. Levy,</p> <p>17 you were asked by the plaintiffs' lawyers to</p> <p>18 provide a review of the literature as it relates</p> <p>19 to the biological plausibility of talcum powder</p> <p>20 and ovarian cancer. Is that right?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A No, that's not correct. What I was --</p> <p>24 I was asked to provide an opin- -- expert opinion</p>

24 (Pages 90 to 93)

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<p style="text-align: right;">Page 94</p> <p>1 on the biological plausibility of the mechanism</p> <p>2 that -- of the ability of exposure of talc and</p> <p>3 its constituent components to cause inflammation</p> <p>4 and/or cancer.</p> <p>5 MS. BROWN:</p> <p>6 Q Do you see those as two different</p> <p>7 things?</p> <p>8 A Yes.</p> <p>9 Q Okay. So you were asked to provide a</p> <p>10 mechanism by which talcum powder could cause</p> <p>11 cancer?</p> <p>12 A No, that's not correct.</p> <p>13 MS. O'DELL:</p> <p>14 Objection to form.</p> <p>15 MS. BROWN:</p> <p>16 Q Okay. Explain it to me.</p> <p>17 A I -- I was asked to provide a -- an</p> <p>18 opinion on the biological plausibility --</p> <p>19 Q Of talcum powder causing cancer?</p> <p>20 A -- of talcum powder leading to the</p> <p>21 biological changes necessary to cause cancer.</p> <p>22 Q Okay. As I understand what you just</p> <p>23 said, you were asked to re- -- to provide an</p> <p>24 opinion on the biological plausibility of talcum</p>	<p style="text-align: right;">Page 96</p> <p>1 some neurological diseases.</p> <p>2 So this was a similar review as -- of</p> <p>3 those topics when asked to examine the biological</p> <p>4 plausibility of a cause and effect; in this case,</p> <p>5 cause being exposure to talcum powder and effect</p> <p>6 being progression to cancer.</p> <p>7 Q Prior to being hired by the plaintiffs'</p> <p>8 lawyers, you had not considered the biological</p> <p>9 plausibility of talcum powder causing ovarian</p> <p>10 cancer. Correct?</p> <p>11 A No. I would say that's not true in</p> <p>12 isolation. And the reason I say that's not true</p> <p>13 is I had been aware of some of the literature and</p> <p>14 certainly some of the press that surrounded the</p> <p>15 suspected associations between talcum powder</p> <p>16 exposure and cancer. So I was familiar with the</p> <p>17 concept, but I had not at the time, until hired</p> <p>18 by the plaintiffs' attorney, spent a significant</p> <p>19 amount of time reviewing the literature and</p> <p>20 developing a written opinion as to that</p> <p>21 biological plausibility.</p> <p>22 Q You have not published your opinion</p> <p>23 contained in -- your opinions contained in the</p> <p>24 report that we marked as Exhibit 2. Is that</p>
<p style="text-align: right;">Page 95</p> <p>1 powder leading to biologic changes that are</p> <p>2 needed to cause cancer. Is that fair?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A So I was asked from -- by the attorneys</p> <p>6 to review the available literature across the</p> <p>7 spectrum of cancer and talcum powder and</p> <p>8 constituent literature to develop an opinion</p> <p>9 around the biological plausibility that exposure</p> <p>10 of -- exposure to talcum powder is</p> <p>11 biologically -- that there is a biologically</p> <p>12 plausible mechanism that that can cause cancer.</p> <p>13 MS. BROWN:</p> <p>14 Q Okay. And that is not something that</p> <p>15 you had done prior to being hired by the</p> <p>16 plaintiffs' lawyers. Fair?</p> <p>17 A Developing such an opinion?</p> <p>18 Q Correct.</p> <p>19 A Or -- or -- so writing such a report,</p> <p>20 no, that is not something I -- I had done prior</p> <p>21 to -- to this. My research has been primarily in</p> <p>22 data integration and the examination of</p> <p>23 mechanistic effects in cancer, rare disease,</p> <p>24 and -- and in diabetes specifically, as well as</p>	<p style="text-align: right;">Page 97</p> <p>1 correct?</p> <p>2 A That is correct.</p> <p>3 Q You have not presented the opinions</p> <p>4 contained in Exhibit 2 at any medical or</p> <p>5 scientific conference; correct?</p> <p>6 A That's correct.</p> <p>7 Q You have not disclosed the opinions</p> <p>8 contained in Exhibit 2 to any of your colleagues;</p> <p>9 correct?</p> <p>10 MS. O'DELL:</p> <p>11 Object to the form.</p> <p>12 A Not at this time, no. Considering I</p> <p>13 had -- I had just finalized the report a short</p> <p>14 time ago, I haven't had the opportunity to</p> <p>15 consider publication, presentation, or -- or</p> <p>16 discussion with colleagues.</p> <p>17 MS. BROWN:</p> <p>18 Q Do you plan to seek publication of the</p> <p>19 information contained in your report in Exhibit</p> <p>20 2?</p> <p>21 A I -- I haven't made a determination at</p> <p>22 this time. It's been a fascinating area to</p> <p>23 research. Certainly there's -- that would</p> <p>24 certainly be a future possibility.</p>

25 (Pages 94 to 97)

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<p style="text-align: right;">Page 98</p> <p>1 Q Does HudsonAlpha --</p> <p>2 First of all, what's your position at</p> <p>3 HudsonAlpha, Doctor?</p> <p>4 A So I'm a faculty investigator, which</p> <p>5 would be analogous to a faculty member at a</p> <p>6 research institution, similar to -- or I should</p> <p>7 take a step back and just --</p> <p>8 To be accurate, HudsonAlpha is a</p> <p>9 private nonprofit research institution, similar</p> <p>10 to Broad Institute, Stowers, et cetera. So we</p> <p>11 are academic in nature, meaning that most of our</p> <p>12 funding or the vast majority of our funding comes</p> <p>13 from grants and contracts. So that's why I say</p> <p>14 it's analogous to faculty at a research</p> <p>15 institution.</p> <p>16 My other responsibilities are the</p> <p>17 management and oversight of the production and</p> <p>18 research laboratories, so that provides us an</p> <p>19 opportunity to work with approximately 1200</p> <p>20 different laboratories from around the world in</p> <p>21 support of roughly 5,000 projects over the last</p> <p>22 nine and a half years. And that's -- it's</p> <p>23 provided a broad spectrum of activities and</p> <p>24 abilities to work in these types of projects.</p>	<p style="text-align: right;">Page 100</p> <p>1 or -- or -- or dispute whether or not those</p> <p>2 ovarian cancer or other cancer types may have had</p> <p>3 a relationship to talcum powder. So the short</p> <p>4 answer being I -- I don't have the information to</p> <p>5 answer that.</p> <p>6 MS. BROWN:</p> <p>7 Q HudsonAlpha has a Code of Ethics. Are</p> <p>8 you familiar with it?</p> <p>9 A Yes.</p> <p>10 Q Are you familiar with the financial</p> <p>11 disclosure requirements of HudsonAlpha?</p> <p>12 A I am.</p> <p>13 Q Have you complied with those in</p> <p>14 connection with your work as an expert witness</p> <p>15 for plaintiffs in this case?</p> <p>16 A I have.</p> <p>17 Q And tell us what you've done to comply</p> <p>18 with HudsonAlpha's Code of Ethics and financial</p> <p>19 disclosure requirements.</p> <p>20 A Their Code of Ethics and financial</p> <p>21 requirement is requirement to disclose any</p> <p>22 relationships that have a financial component</p> <p>23 over -- I don't recall the minimum amount, but it</p> <p>24 is -- it is fairly modest, hundreds of dollars.</p>
<p style="text-align: right;">Page 99</p> <p>1 And then I also oversee the clinical</p> <p>2 laboratories as well. And adult oncology is a</p> <p>3 major focus of that research. I currently lead</p> <p>4 the largest profiling effort in adult cancer in</p> <p>5 the nation, which involves 15 national cancer</p> <p>6 institutes. And ovarian cancer is a component of</p> <p>7 that research, although not the only cancer that</p> <p>8 we research in that -- in that's -- in that</p> <p>9 program.</p> <p>10 Q None of the 5,000 projects you just</p> <p>11 mentioned have dealt with talc. Is that fair?</p> <p>12 A That is fair.</p> <p>13 Q And none of the work at the clinical</p> <p>14 labs that you just mentioned have dealt with</p> <p>15 talc; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object.</p> <p>18 A I am -- I would say there's a</p> <p>19 statistical probability that some of the ovarian</p> <p>20 cancer samples that have been observed in the</p> <p>21 clinical laboratory may very well have</p> <p>22 been -- have come from patients exposed to talcum</p> <p>23 powder. But I have no direct knowledge of that,</p> <p>24 nor have we performed any testing to confirm</p>	<p style="text-align: right;">Page 101</p> <p>1 And that reporting requirement is the -- is -- is</p> <p>2 for the previous year, and it is due in July, I</p> <p>3 believe is the time frame, although I'd have to</p> <p>4 make sure. It's -- I know it's not the end of</p> <p>5 the calendar year. So on my next disclosure,</p> <p>6 this, of course, activity would be disclosed.</p> <p>7 In addition to that, via</p> <p>8 conversation -- regular review with the president</p> <p>9 of the institution, I provide a general report on</p> <p>10 consulting activities; for example, these</p> <p>11 activities.</p> <p>12 HudsonAlpha's policy is faculty members</p> <p>13 are allowed up to 20 percent of your time towards</p> <p>14 consulting activities that have a relationship to</p> <p>15 your research area, such as the evaluation of the</p> <p>16 biologically plausible mechanism of talc in</p> <p>17 ovarian cancer. So based on both the timing of</p> <p>18 the Code of Ethics with regards to the financial</p> <p>19 disclosure as well as the ad hoc reporting of</p> <p>20 consulting engagements with the president of the</p> <p>21 institution, I'm in compliance with the current</p> <p>22 policies of HudsonAlpha.</p> <p>23 Q The president of HudsonAlpha is aware</p> <p>24 of your opinions in this case?</p>

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<p style="text-align: right;">Page 102</p> <p>1 A I have not discussed my opinions</p> <p>2 specifically to this case with him; just the</p> <p>3 general knowledge that I was asked to participate</p> <p>4 as an expert witness. He didn't ask, and I</p> <p>5 didn't provide the content.</p> <p>6 Q No one at HudsonAlpha is aware of your</p> <p>7 opinion that talcum powder causes chronic</p> <p>8 inflammation which can cause ovarian cancer? Is</p> <p>9 that right?</p> <p>10 A I have -- I have not specifically</p> <p>11 shared the contents of the report or -- or my</p> <p>12 opinions widely at HudsonAlpha.</p> <p>13 Q Did you disclose last July that you had</p> <p>14 already been hired and submitted invoices to the</p> <p>15 plaintiffs' lawyers?</p> <p>16 A I'm sure I did.</p> <p>17 Q Do you have that documentation?</p> <p>18 A No. It's -- it's an electronic</p> <p>19 disclosure. It's not actually done on paper.</p> <p>20 Q One of the things that HudsonAlpha does</p> <p>21 is it partners with the University of Alabama in</p> <p>22 a comprehensive cancer center; correct?</p> <p>23 A No, that wouldn't be correct.</p> <p>24 HudsonAlpha is very specific --</p>	<p style="text-align: right;">Page 104</p> <p>1 members on both institutions.</p> <p>2 MS. BROWN:</p> <p>3 Q Fair to say, then, Doctor, you have not</p> <p>4 participated in any work with the University of</p> <p>5 Alabama's Comprehensive Cancer Center?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A No, that's not true.</p> <p>9 MS. BROWN:</p> <p>10 Q Have you worked with the University of</p> <p>11 Alabama's Comprehensive Cancer Center on projects</p> <p>12 involving ovarian cancer?</p> <p>13 MS. O'DELL:</p> <p>14 Objection. Asked and answered.</p> <p>15 A I would -- I would have to review the</p> <p>16 specific projects that we've -- we've done to</p> <p>17 answer that.</p> <p>18 As the codirector of a core facility</p> <p>19 for the University of Alabama Comprehensive</p> <p>20 Cancer Center, it is likely that we've worked on</p> <p>21 some projects related to ovarian cancer, but I</p> <p>22 can't specifically name them. They are -- I</p> <p>23 would -- I would characterize them as infrequent.</p> <p>24 MS. BROWN:</p>
<p style="text-align: right;">Page 103</p> <p>1 And you may be more familiar with this</p> <p>2 than I.</p> <p>3 They're very specific with their use of</p> <p>4 the word "partnership" and they're, in fact, very</p> <p>5 specific that they do not engage in a -- anything</p> <p>6 titled "a partnership." So they -- I would not</p> <p>7 characterize them as a partner of the University</p> <p>8 of Alabama Cancer Center.</p> <p>9 We certainly have -- there are faculty</p> <p>10 members at University of Alabama Birmingham who</p> <p>11 are -- have adjunct appointments at HudsonAlpha,</p> <p>12 just as I have appointments at University of</p> <p>13 Alabama Birmingham and I am a member of their</p> <p>14 cancer center.</p> <p>15 Q Are you aware of the work that</p> <p>16 HudsonAlpha does with the University of Alabama's</p> <p>17 Comprehensive Cancer Center?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form. Asked and</p> <p>20 answered.</p> <p>21 A I'm aware of some of the work, but I --</p> <p>22 certainly I -- I don't -- I don't necessarily</p> <p>23 have knowledge of the full spectrum of those</p> <p>24 projects, given that they involve many faculty</p>	<p style="text-align: right;">Page 105</p> <p>1 Q Have any of those projects attempted to</p> <p>2 research the potential causes of ovarian cancer?</p> <p>3 A Again, I'd have -- I'd have to review</p> <p>4 the projects. They're certainly --</p> <p>5 fundamentally, most of the questions regarding</p> <p>6 the analysis of cancer samples are routinely to</p> <p>7 investigate their cause or their treatment. So I</p> <p>8 would -- I would answer that question as highly</p> <p>9 likely.</p> <p>10 Q Would you agree the cause of ovarian</p> <p>11 cancer remains unknown today?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A No, I would -- I would -- I would not</p> <p>15 agree that it -- I would not agree to that</p> <p>16 general statement.</p> <p>17 MS. BROWN:</p> <p>18 Q What are the causes of ovarian cancer</p> <p>19 in your mind, Doctor?</p> <p>20 A Well, the -- the causes of -- of</p> <p>21 a -- of any number of cancers, including ovarian</p> <p>22 cancer, are probably more well understood now</p> <p>23 than ever, and their complexities I think now are</p> <p>24 just beginning to be appreciated in the sense</p>

27 (Pages 102 to 105)

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<p style="text-align: right;">Page 106</p> <p>1 that cancer is a disease of unregulated cell</p> <p>2 growth.</p> <p>3 Back to our earlier con- -- earlier</p> <p>4 conversation, some of the fundamental facts that</p> <p>5 we had discussed and, in fact, I think well</p> <p>6 replicated in a number of sources, as you pointed</p> <p>7 out to me, you know, illustrate that there's a</p> <p>8 milieu of genetic change leading to cellular</p> <p>9 transformation, and that cellular damage, if we</p> <p>10 consolidate that as cellular damage, then has to</p> <p>11 work in concert with a number of other events</p> <p>12 providing the right environment for a tumor to</p> <p>13 grow, such as inflammation, chronic or acute.</p> <p>14 And, so, the -- you know, the -- the -- you know,</p> <p>15 giving a singular cause would be inappropriate.</p> <p>16 But I would say the mechanistic causes</p> <p>17 of cancer are reasonably well understood, but how</p> <p>18 those apply to the wide diversity of cancer types</p> <p>19 remains an area of active investigation.</p> <p>20 I think what's interesting on cancer in</p> <p>21 general is that there's no -- really no longer a</p> <p>22 bucket diagnosis. It is -- it -- lung cancer is</p> <p>23 more complex than lung cancer and ovarian cancer,</p> <p>24 certainly with the --</p>	<p style="text-align: right;">Page 108</p> <p>1 Now, the -- whether that represents the</p> <p>2 complete milieu of possibilities is -- is what is</p> <p>3 currently under research.</p> <p>4 MS. BROWN:</p> <p>5 Q Were you aware that the University of</p> <p>6 Alabama Comprehensive Cancer Center is an NCI</p> <p>7 center, National Cancer Institute?</p> <p>8 A Yes. It's -- it's not only an</p> <p>9 NCI-designated center; it's an NCI-designated</p> <p>10 comprehensive cancer center, which is a slightly</p> <p>11 different classification. It's a -- there's more</p> <p>12 criteria for a cancer center to meet to become</p> <p>13 comprehensive.</p> <p>14 Q What does it mean to be an NCI center,</p> <p>15 to you, if you know?</p> <p>16 A Stated very simply, it means you have</p> <p>17 a -- your cancer center is funded by a support</p> <p>18 grant directly from the National Cancer Institute</p> <p>19 to provide -- that supports not only patient care</p> <p>20 but also supports basic research, epidemiology</p> <p>21 and -- and health outcomes research in cancer.</p> <p>22 So, in a nutshell, it is a fairly</p> <p>23 comprehensive grant that supports a wide variety</p> <p>24 of work within a cancer center that extends</p>
<p style="text-align: right;">Page 107</p> <p>1 As I'm sure you're well aware, with the</p> <p>2 molecular subtypes and other things, it's a</p> <p>3 complicated disease as well.</p> <p>4 So to summarize that is -- to summarize</p> <p>5 all of that complexity by saying that the cause</p> <p>6 is known or unknown I think would vastly</p> <p>7 underestimate the -- our current state of the art</p> <p>8 or knowledge of how complex cancer is as a</p> <p>9 condition.</p> <p>10 Q Sure.</p> <p>11 Scientists, researchers, public health</p> <p>12 authorities continue to investigate the mechanism</p> <p>13 by which ovarian cancer is caused. Correct?</p> <p>14 A That's correct.</p> <p>15 Q We do not, sitting here today in 2019,</p> <p>16 have a complete understanding of the etiology of</p> <p>17 ovarian cancer. Correct?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I would say we have substantial</p> <p>21 knowledge of factors and exposures that either</p> <p>22 predispose or directly cause cancer in a large</p> <p>23 number of -- large number of cancer areas,</p> <p>24 including ovarian cancer.</p>	<p style="text-align: right;">Page 109</p> <p>1 beyond basic -- basic care.</p> <p>2 Q The National Cancer Institute has</p> <p>3 funded a number of projects that the scientists</p> <p>4 at HudsonAlpha are working on. Is that fair?</p> <p>5 A I'd have to certainly review the grant</p> <p>6 portfolio. But I'm certain that, since I myself</p> <p>7 have funding from that cancer center, yes, the</p> <p>8 NCI does fund some -- some number of</p> <p>9 investigators at HudsonAlpha.</p> <p>10 Q And you consider the NCI to be a</p> <p>11 reputable public health authority; correct?</p> <p>12 A No, not necessarily. The NCI is really</p> <p>13 not a public health authority. The N -- the NCI</p> <p>14 is a -- is a scientific administration center</p> <p>15 within the National Institutes of Health.</p> <p>16 Now, I'm speaking of their extramural</p> <p>17 programs. The NCI also have intramural programs,</p> <p>18 where they have their own researchers and their</p> <p>19 own projects. I'm less familiar with those</p> <p>20 activities.</p> <p>21 But together, I would state that the</p> <p>22 NCI is a -- I don't have -- I guess I have not</p> <p>23 had any experience with the NCI that would lead</p> <p>24 me to say that they are an authoritative public</p>

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<p style="text-align: right;">Page 110</p> <p>1 health authority.</p> <p>2 Q Before forming your opinions in this</p> <p>3 case, Dr. Levy, did you look to see what the NCI</p> <p>4 states about whether talcum powder causes ovarian</p> <p>5 cancer?</p> <p>6 A I believe I did see, from a number of</p> <p>7 statements, certainly potentially from the NCI,</p> <p>8 regarding the complete opinion and -- and</p> <p>9 knowledge base for the role of talcum powder in</p> <p>10 ovarian cancer.</p> <p>11 Q Do you recall that the NCI has</p> <p>12 concluded that there's inadequate evidence that</p> <p>13 talcum powder increases the risk of ovarian</p> <p>14 cancer?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A Which -- what specifically are you</p> <p>18 referring to? I -- I wouldn't be able to answer</p> <p>19 that accurately without knowing which specific</p> <p>20 report or statement that you're referring to.</p> <p>21 MS. BROWN:</p> <p>22 Q I'm wondering if, sitting here today,</p> <p>23 you recall looking at information about the</p> <p>24 classification of risk factors for ovarian cancer</p>	<p style="text-align: right;">Page 112</p> <p>1 you are prepared to offer the opinion that talcum</p> <p>2 powder causes ovarian cancer.</p> <p>3 A I don't -- I don't think we have the</p> <p>4 complete information for a sing- -- you know, to</p> <p>5 have the opinion of a singular cause. But, at</p> <p>6 the same time, my opinions are that, as stated in</p> <p>7 the report, there's a clear and well-evidenced</p> <p>8 biologically plausible role for talcum powder</p> <p>9 leading to ovarian cancer.</p> <p>10 Q On page 2 of your report, the second</p> <p>11 full paragraph that begins "My report</p> <p>12 consists" --</p> <p>13 You with me?</p> <p>14 A Yes.</p> <p>15 Q -- you state -- you reference your</p> <p>16 conclusions regarding this cause-and-effect</p> <p>17 relationship.</p> <p>18 Do you see that?</p> <p>19 A I do.</p> <p>20 Q Do you mean by that that you have an</p> <p>21 opinion that talcum powder causes the effect of</p> <p>22 ovarian cancer?</p> <p>23 A No. That -- that wasn't the meaning of</p> <p>24 that statement of cause and effect. It was -- it</p>
<p style="text-align: right;">Page 111</p> <p>1 as done by the NCI.</p> <p>2 A I don't recall that specifically. I</p> <p>3 don't also recall seeing any statements from the</p> <p>4 NCI regarding safety of any product.</p> <p>5 Q In forming your opinions in this case,</p> <p>6 Dr. Levy, did you consider the conclusions of</p> <p>7 public health authorities like the FDA, the NCI,</p> <p>8 NIH as it relates to talcum powder in ovarian</p> <p>9 cancer?</p> <p>10 A So I certainly considered information</p> <p>11 from each of those entities. But I would make a</p> <p>12 statement I don't -- I don't recall from any of</p> <p>13 those entities seeing a single conclusion.</p> <p>14 Q Is it your opinion, Dr. Levy, that</p> <p>15 talcum powder causes ovarian cancer?</p> <p>16 A I wasn't asked to provide an opinion if</p> <p>17 talcum powder causes cancer. I was -- I was</p> <p>18 asked to develop an opinion as to the biological</p> <p>19 plausibility of -- of talcum powder leading</p> <p>20 to -- leading to change.</p> <p>21 Now, that's what I was asked from the</p> <p>22 attorneys. If you're asking -- are you asking me</p> <p>23 what my opinion is --</p> <p>24 Q Well, I want to know if, in this case,</p>	<p style="text-align: right;">Page 113</p> <p>1 was a -- more of a general statement of a cause</p> <p>2 being exposure to talc and effect being that</p> <p>3 biologically plausible mechanism.</p> <p>4 Q You mentioned a moment ago that you</p> <p>5 don't think we have the complete info on a</p> <p>6 singular cause of ovarian cancer. Is that right?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form.</p> <p>9 A Sorry. Let me read your question</p> <p>10 again.</p> <p>11 I have -- I have not seen any evidence</p> <p>12 that suggests that there is a singular cause of</p> <p>13 ovarian cancer.</p> <p>14 MS. BROWN:</p> <p>15 Q You have not seen sufficient evidence</p> <p>16 to suggest that talcum powder could be one of the</p> <p>17 causes of ovarian cancer; correct?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I would disagree. As -- as stated,</p> <p>21 the -- I have not seen evidence that there's a</p> <p>22 singular cause of ovarian cancer. I think there</p> <p>23 is ample evidence that there are a multitude of</p> <p>24 mechanisms that you can get cellular damage and</p>

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<p style="text-align: right;">Page 114</p> <p>1 cellular change within the ovary which then leads</p> <p>2 to malignant transformation, and that, as stated</p> <p>3 in the report, there's a biologically plausible</p> <p>4 mechanism that exposure to talcum powder and its</p> <p>5 constituents can create those necessary changes.</p> <p>6 MS. BROWN:</p> <p>7 Q Do you believe, Doctor, there's</p> <p>8 sufficient evidence that talcum powder, through</p> <p>9 chronic inflammation, causes ovarian cancer in</p> <p>10 some individuals?</p> <p>11 A No. That -- that was not my -- not my</p> <p>12 opinion or statement. And I would say</p> <p>13 specifically chronic inflammation is, again,</p> <p>14 narrowing the focus in an inappropriate way, and</p> <p>15 the evidence doesn't illustrate that chronic</p> <p>16 inflammation is a singular sufficient detail or,</p> <p>17 I should say, effect to result in ovarian cancer.</p> <p>18 It's certainly a factor, as -- as well described</p> <p>19 in the -- in the literature.</p> <p>20 And -- and, again, I would defer to</p> <p>21 other expert reports that have similar opinions</p> <p>22 regarding inflammation, chronic inflammation</p> <p>23 being one of them.</p> <p>24 And it may be important to provide an</p>	<p style="text-align: right;">Page 116</p> <p>1 of observations and studies that</p> <p>2 have -- certainly exist. And, again, their</p> <p>3 review and -- and content is what went to the</p> <p>4 opinions in my report.</p> <p>5 Q And most of the studies that you cite,</p> <p>6 Dr. Levy, talking about chronic inflammation</p> <p>7 refer to chronic inflammation as a hypothesis of</p> <p>8 one of the ways cancer might form in the ovary.</p> <p>9 Correct?</p> <p>10 MS. O'DELL:</p> <p>11 Object to the form.</p> <p>12 A Let me -- sorry. Let me read your</p> <p>13 question.</p> <p>14 No. I would disagree. At least,</p> <p>15 certainly not most of the studies that I cite.</p> <p>16 MS. BROWN:</p> <p>17 Q Do you believe chronic inflammation is</p> <p>18 an established mechanism of ovarian cancer?</p> <p>19 A Yes, in the sense that chronic</p> <p>20 inflammation is a well-established mechanism of</p> <p>21 cancer in general, including ovarian cancer.</p> <p>22 This is first observed in the 1800s and has since</p> <p>23 been -- become well-established in the -- in the</p> <p>24 cancer field that inflammation plays a</p>
<p style="text-align: right;">Page 115</p> <p>1 important distinction that cellular damage or</p> <p>2 what we can refer to as acute inflammation can</p> <p>3 cause -- certainly has been shown and is</p> <p>4 well-evidenced that it causes -- can lead to</p> <p>5 molecular changes that can lead to cancer.</p> <p>6 Chronic inflammation is a slightly --</p> <p>7 is in a slightly different biological perspective</p> <p>8 in that it provides the correct environment for</p> <p>9 those cancerous changes to take hold and allow</p> <p>10 malignant transformation, as I mentioned.</p> <p>11 So I -- I do view them as working in</p> <p>12 concert but not necessarily independent. So when</p> <p>13 you ask a question that specifically narrows it</p> <p>14 to chronic inflammation or even acute</p> <p>15 inflammation in a singular fashion, you know, my</p> <p>16 answers will largely be the same, that that's, in</p> <p>17 and of itself, is too limited to describe as a</p> <p>18 specific cause, singular or otherwise, of ovarian</p> <p>19 cancer or of cancer in general.</p> <p>20 Q You'd agree that the research regarding</p> <p>21 whether chronic inflammation can cause ovarian</p> <p>22 cancer is ongoing?</p> <p>23 A Yes, I would agree it is -- it is</p> <p>24 ongoing research. But there are a large number</p>	<p style="text-align: right;">Page 117</p> <p>1 significant role in both the initiation as well</p> <p>2 as progression of cancer.</p> <p>3 Q What methodology did you employ for</p> <p>4 coming to the opinion that chronic inflammation</p> <p>5 is a well-established cause of ovarian cancer?</p> <p>6 A Just general mechanism in terms of</p> <p>7 evaluating biological plausibility.</p> <p>8 Q I understand, Dr. Levy, you have a</p> <p>9 general opinion that chronic inflammation can</p> <p>10 lead to some cancer. Is that right?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form. Misstates his</p> <p>13 testimony.</p> <p>14 A I -- I have an opinion regarding the</p> <p>15 role and importance of inflammation in the</p> <p>16 initiation and progression of cancer.</p> <p>17 MS. BROWN:</p> <p>18 Q And, as it relates to ovarian cancer,</p> <p>19 what methodology did you employ to arrive at your</p> <p>20 conclusion that chronic inflammation is an</p> <p>21 established cause of ovarian cancer?</p> <p>22 A I -- I did not arrive at that specific</p> <p>23 conclusion, nor was I asked to.</p> <p>24 Q You do not believe that chronic</p>

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<p style="text-align: right;">Page 118</p> <p>1 inflammation has been established as a cause of</p> <p>2 ovarian cancer; correct?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A No, that -- that's not what I said.</p> <p>6 MS. BROWN:</p> <p>7 Q Explain it to me.</p> <p>8 A I've stated that chronic inflammation</p> <p>9 or inflammation in general, including chronic and</p> <p>10 acute infor -- inflammation, is a component and a</p> <p>11 necessary component for the initiation and</p> <p>12 progression of -- of cancer as we understand it</p> <p>13 today. And, in that, cancer, certainly ovarian</p> <p>14 cancer as well as a variety of other cancer</p> <p>15 types, is included.</p> <p>16 Q What methodology did you employ to</p> <p>17 arrive at the conclusion that ovarian cancer is</p> <p>18 one of the cancers that can be caused by chronic</p> <p>19 inflammation?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Misstates his</p> <p>22 testimony.</p> <p>23 A Yeah. Again, we're not -- I'm not</p> <p>24 making a specific causal opinion with respect to</p>	<p style="text-align: right;">Page 120</p> <p>1 from animal models to in vitro studies, in vivo</p> <p>2 studies, cohort studies, case-control studies.</p> <p>3 There was quite a broad spectrum of information</p> <p>4 across a large number of years.</p> <p>5 Q Do you believe you reviewed the</p> <p>6 totality of the epidemiology on talcum powder use</p> <p>7 and ovarian cancer?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A I -- I reviewed the available studies</p> <p>11 that appeared to be relevant for the -- for the</p> <p>12 opinions that are expressed in my report.</p> <p>13 MS. BROWN:</p> <p>14 Q And when you say "available," what do</p> <p>15 you mean?</p> <p>16 A Meaning that I could -- I could</p> <p>17 discover in the scientific literature.</p> <p>18 Q Did you conduct your own literature</p> <p>19 searches in connection with your work in this</p> <p>20 case?</p> <p>21 A I did.</p> <p>22 Q How did you go about finding the</p> <p>23 totality of the evidence relating to whether</p> <p>24 talcum powder causes ovarian cancer?</p>
<p style="text-align: right;">Page 119</p> <p>1 any -- whether -- whether inflammation, talcum</p> <p>2 powder use or other exposures. I -- my -- my</p> <p>3 opinion in the report is -- is -- was not asked</p> <p>4 to be a causal opinion.</p> <p>5 MS. BROWN:</p> <p>6 Q You reference on page 2 of your report</p> <p>7 that your opinions are based on assessing and</p> <p>8 weighing the totality of the evidence, including</p> <p>9 relevant literature and available documentation</p> <p>10 and your experience as a geneticist and</p> <p>11 scientific researcher. Do you see that?</p> <p>12 A Yes.</p> <p>13 Q What do you mean by "the totality of</p> <p>14 the evidence"?</p> <p>15 A All of the evidence available at the</p> <p>16 time that I was researching this report.</p> <p>17 Q All of the evidence concerning what?</p> <p>18 A Concerning a variety of subjects</p> <p>19 surrounding ovarian cancer, talcum powder use,</p> <p>20 and then inflammation and related subjects as my</p> <p>21 literature review and review of available</p> <p>22 information progressed.</p> <p>23 So there was a, I guess, a large number</p> <p>24 of tangential directions that -- that I examined,</p>	<p style="text-align: right;">Page 121</p> <p>1 A So the -- my methodology for the</p> <p>2 literature review in establishing my opinion</p> <p>3 regarding the biological plausibility of talcum</p> <p>4 powder exposure inflammation and its potential</p> <p>5 role in ovarian cancer was based on, you know, my</p> <p>6 activities and many other literature searches, so</p> <p>7 using a variety of computational tools and -- and</p> <p>8 web-based resources, from journals to, I would</p> <p>9 say, primarily PubMed being a resource, but also</p> <p>10 ISI, Web of Science, Google Scholar and a variety</p> <p>11 of -- bioRxiv and I'm sure a number of other</p> <p>12 sources. But those were probably the more</p> <p>13 primary resources for establishing what</p> <p>14 literature was available.</p> <p>15 Q Did you ask the plaintiffs' lawyers for</p> <p>16 any scientific literature that you used in</p> <p>17 forming your opinions in this case?</p> <p>18 A What do you mean by "ask"? There</p> <p>19 is -- as far as did I ask for their similar</p> <p>20 process, no.</p> <p>21 There were some papers that I had</p> <p>22 identified but was not able to access the full</p> <p>23 content via the libraries that I have access to.</p> <p>24 So in some of those cases, specific references</p>

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<p>1 that I provided, those full -- that full content</p> <p>2 was provided by the plaintiffs' lawyer to allow</p> <p>3 me to review it.</p> <p>4 Q Did the plaintiffs' lawyers give you a</p> <p>5 set of epidemiology on which you're relying on to</p> <p>6 form your opinion?</p> <p>7 A No, they did not.</p> <p>8 Q If I look at your report, I see a</p> <p>9 reference list and then a separate Exhibit B. Is</p> <p>10 that right?</p> <p>11 A Yes.</p> <p>12 Q So, for example, on page 18 of your</p> <p>13 report, you have a list of literature cited.</p> <p>14 Correct?</p> <p>15 A Yes.</p> <p>16 Let me make sure I have the page</p> <p>17 correct.</p> <p>18 Yes, beginning on page 18.</p> <p>19 Q Is everything that appears in the</p> <p>20 literature-cited list something that you found on</p> <p>21 your own, Dr. Levy?</p> <p>22 A I would have to review the -- the list.</p> <p>23 But there are certainly --</p> <p>24 Let me --</p>	<p>1 relying on information in that article to form</p> <p>2 your opinions in this case?</p> <p>3 A No. I'm not relying on any singular</p> <p>4 article or source to form my opinion on the case.</p> <p>5 Q Are you relying in part on the</p> <p>6 information contained in the Blount article?</p> <p>7 A Since I include it in the cited</p> <p>8 literature, certainly in some -- in some part.</p> <p>9 Q What information are you relying on in</p> <p>10 the Blount article?</p> <p>11 A I would have to review the article to</p> <p>12 remind myself where the --</p> <p>13 Q Take a look at it. We'll pull it right</p> <p>14 now.</p> <p>15 What about Paoletti on page 22? Was</p> <p>16 that something you found on your own or did the</p> <p>17 lawyers give you that?</p> <p>18 A So Paoletti --</p> <p>19 Q Uh-huh.</p> <p>20 A Page 22?</p> <p>21 Q Uh-huh.</p> <p>22 A Actually, the Paoletti one is familiar.</p> <p>23 That's an interesting one because it's in</p> <p>24 Italian.</p>
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<p>1 I believe the Saed abstracts, as an</p> <p>2 example --</p> <p>3 Let me see if there are --</p> <p>4 No. I -- I believe, in the literature</p> <p>5 cited, there are certainly some number of</p> <p>6 examples of information that was provided during</p> <p>7 the course of the development of my report from</p> <p>8 the plaintiffs' attorneys in terms of literature</p> <p>9 for my consideration, but that in no case -- in</p> <p>10 every case it was provided as a -- as</p> <p>11 information.</p> <p>12 The vast majority or nearly the</p> <p>13 totality of this was information that I had --</p> <p>14 that I indeed discovered myself and shared with</p> <p>15 the -- the attorneys, but certainly not complete.</p> <p>16 Q On page 18 you cite an article by</p> <p>17 Blount.</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q Was that given to you by the</p> <p>21 plaintiffs' lawyers?</p> <p>22 A I'd have to look at my records. I</p> <p>23 don't recall.</p> <p>24 Q Off of the top of your head, are you</p>	<p>1 Q Are you relying on the information in</p> <p>2 the Paoletti article to form your opinions in the</p> <p>3 case?</p> <p>4 A Again, the -- I wasn't relying on any</p> <p>5 singular article but instead tried to present and</p> <p>6 provide reference to as comprehensive a</p> <p>7 collection of relevant literature in this -- in</p> <p>8 this space as possible, of which Paoletti,</p> <p>9 although being in Italian, there were some --</p> <p>10 enough translated aspects of that that it was</p> <p>11 worthy to include in the -- in that cited</p> <p>12 literature as being relevant to the -- to</p> <p>13 those -- to those opinions.</p> <p>14 Q Just to make sure we get on the same</p> <p>15 page here, Dr. Levy, when I ask are you relying</p> <p>16 on something, I don't mean by that question to</p> <p>17 suggest it's the only thing you're relying on.</p> <p>18 And I'll try to say "in part" to make it easy for</p> <p>19 us. Okay?</p> <p>20 A Right. Just want to be -- make sure</p> <p>21 we're clear.</p> <p>22 Q Absolutely. So do I.</p> <p>23 And I want to know are you relying in</p> <p>24 part on anything in the Paoletti article to form</p>

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<p style="text-align: right;">Page 126</p> <p>1 your opinions in this case?</p> <p>2 A I would say in -- in part. As far as</p> <p>3 my opinions regarding the biologically plausible</p> <p>4 mechanism that was presented, no, it does not</p> <p>5 rely on that specific conclusions of that paper</p> <p>6 but, rather, that paper was included because of</p> <p>7 its results regarding asbestos contamination in</p> <p>8 industrial talc, which only support -- add</p> <p>9 support to the mechanism that I presented in the</p> <p>10 report.</p> <p>11 Q Is your opinion in this case, Doctor,</p> <p>12 based on an assumption that baby powder contains</p> <p>13 asbestos?</p> <p>14 A No, it is not.</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 MS. BROWN:</p> <p>18 Q Is your opinion in this case based on</p> <p>19 an assumption that baby powder contains</p> <p>20 fragrances?</p> <p>21 MS. O'DELL:</p> <p>22 Objection to form.</p> <p>23 A My -- my opinion considers the totality</p> <p>24 of the constituent components of baby powder,</p>	<p style="text-align: right;">Page 128</p> <p>1 presented.</p> <p>2 MS. BROWN:</p> <p>3 Q Do you believe that baby talc alone can</p> <p>4 cause inflammation that may lead to ovarian</p> <p>5 cancer?</p> <p>6 A Based on my review of the literature,</p> <p>7 there are a number of studies, both of those</p> <p>8 involving human studies in terms of case</p> <p>9 controls, as well as a number of animal studies</p> <p>10 and then, more specifically, in vitro studies</p> <p>11 that look at talcum powder and its ability to</p> <p>12 produce clear markers of inflammation.</p> <p>13 I am -- the -- I am not aware of any</p> <p>14 specific testing that looked at platy talc</p> <p>15 individually as a singular component without</p> <p>16 the -- or out of the context of the products we</p> <p>17 were just describing in a similar analysis. So I</p> <p>18 don't -- I don't know that answer.</p> <p>19 Q Is it your opinion that</p> <p>20 Johnson & Johnson baby powder products are</p> <p>21 contaminated with asbestos?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form. Asked and</p> <p>24 answered.</p>
<p style="text-align: right;">Page 127</p> <p>1 Shower to Shower, you know, under -- either, as</p> <p>2 we've been referring to it simply as talc or</p> <p>3 talcum powder or by trade names such as</p> <p>4 Johnson & Johnson or Shower to Shower, so the --</p> <p>5 my opinions, as stated in the report, being</p> <p>6 reasonably -- or trying to be reasonably</p> <p>7 comprehensive. Therefore, it's not, you know,</p> <p>8 limited to any -- any singular component, whether</p> <p>9 it be majority or minority, in the -- in the</p> <p>10 talcum powder products, as I just stated.</p> <p>11 MS. BROWN:</p> <p>12 Q Is your opinion in this case based on</p> <p>13 an assumption that Johnson & Johnson baby powder</p> <p>14 products contain heavy metals?</p> <p>15 MS. O'DELL:</p> <p>16 Objection to form.</p> <p>17 A Again, similar to the earlier</p> <p>18 statement, the opinion is not subject to</p> <p>19 any -- any singular component. I think the</p> <p>20 information regarding the -- in deferring to some</p> <p>21 of the other experts regarding the knowledge of</p> <p>22 constituent components, whether they be heavy</p> <p>23 metals or asbestos, only helps to support the</p> <p>24 biological plausibility of the mechanism I</p>	<p style="text-align: right;">Page 129</p> <p>1 A I -- I -- I have -- I have been</p> <p>2 provided expert report, and some of those are</p> <p>3 referenced in the -- in the report, as we were</p> <p>4 describing, that describe testing of a number</p> <p>5 of -- number of samples,</p> <p>6 included -- Johnson & Johnson included in that,</p> <p>7 that showed how they -- that the results of those</p> <p>8 reports showed contamination by asbestos or --</p> <p>9 or -- or asbestos-like fiber. So, therefore,</p> <p>10 I've been presented with that evidence.</p> <p>11 MS. BROWN:</p> <p>12 Q Have you relied on that evidence in</p> <p>13 forming your opinions in this case?</p> <p>14 A Again, no, not -- not as a singular</p> <p>15 evidence. So, as we just discussed a moment ago,</p> <p>16 that is a component piece of evidence that</p> <p>17 leads -- and is supportive of the biologically</p> <p>18 plausible mechanism described in the report.</p> <p>19 You know, certainly, it is inarguable</p> <p>20 that asbestos and asbestos-like fibers cause</p> <p>21 inflammation. There's also ample evidence of the</p> <p>22 inflammatory effects of talc. And -- and talc</p> <p>23 pleurodesis, for example, is -- is designed to</p> <p>24 produce inflammatory response as a treatment.</p>

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<p>1 So I think, again, similar to the</p> <p>2 relationship of asbestos and inflammation, it's a</p> <p>3 well-established scientific fact that talc has an</p> <p>4 inflammatory role now. Or I should say as of</p> <p>5 today.</p> <p>6 Q Have you attempted to quantify, based</p> <p>7 on the reports of Dr. Longo that you reviewed,</p> <p>8 how much asbestos contamination is in</p> <p>9 Johnson & Johnson baby powder products?</p> <p>10 MS. O'DELL:</p> <p>11 Objection. Vague as to form.</p> <p>12 A I --</p> <p>13 MS. O'DELL:</p> <p>14 As to the volume and time contained,</p> <p>15 et cetera.</p> <p>16 A My -- my answer is simply that I wasn't</p> <p>17 asked to quantify that as part of my report.</p> <p>18 MS. BROWN:</p> <p>19 Q Whether there is asbestos in Johnson &</p> <p>20 Johnson baby powder products or not does not</p> <p>21 impact your opinions in this case; is that right?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A The opinions regarding the biological</p>	<p>1 in any of the above-referenced studies.</p> <p>2 MS. O'DELL:</p> <p>3 Objection. Misstates his testimony.</p> <p>4 A So reading -- reading back my</p> <p>5 testimony --</p> <p>6 MS. BROWN:</p> <p>7 Q So, Doctor, I see that you're looking</p> <p>8 at the realtime?</p> <p>9 A Yes.</p> <p>10 Q To get clarification on the question?</p> <p>11 A No. To -- to remem- -- to -- you asked</p> <p>12 me a question about my statement.</p> <p>13 Q Correct.</p> <p>14 A And I was reviewing specifically what I</p> <p>15 had stated so I could answer your question</p> <p>16 accurately.</p> <p>17 Q Terrific. So I want to know what you</p> <p>18 were talking about when you said you were unable</p> <p>19 to discover the contamination rate.</p> <p>20 A To clarify, I was not asked to estimate</p> <p>21 or determine the contamination rate, and my</p> <p>22 statement regarding that was in reference to the</p> <p>23 material I reviewed and the literature that is</p> <p>24 referenced in my report. I don't recall in any</p>
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<p>1 plausibility described in my report and its</p> <p>2 relationship to asbestos are somewhat separate,</p> <p>3 meaning that I have -- I was not able to discover</p> <p>4 what the contamination rate or content of</p> <p>5 asbestos was in any of the referenced studies</p> <p>6 through the course of my report, so, therefore, I</p> <p>7 can't comment on the likelihood or -- of -- of</p> <p>8 how many or any -- or any or all of those samples</p> <p>9 contain asbestos.</p> <p>10 MS. BROWN:</p> <p>11 Q And sounds like you did some work</p> <p>12 attempting to see if you could calculate a</p> <p>13 contamination rate. Is that what you were</p> <p>14 describing?</p> <p>15 MS. O'DELL:</p> <p>16 Object -- object to the form.</p> <p>17 Misstates his testimony.</p> <p>18 A No. No, not at all. I stated that I</p> <p>19 didn't have information available to assess</p> <p>20 either -- either way.</p> <p>21 MS. BROWN:</p> <p>22 Q Tell me what you meant when you</p> <p>23 testified that you were not able to discover what</p> <p>24 the contamination rate or content of asbestos was</p>	<p>1 of those studies observing a specific statement</p> <p>2 of amount of asbestos in the talcum powder</p> <p>3 products that were under study. So, therefore, I</p> <p>4 am not able to form an opinion surrounding that</p> <p>5 contamination rate.</p> <p>6 Q Would the same be true, Doctor, for</p> <p>7 heavy metals?</p> <p>8 A Yes, that's correct.</p> <p>9 Q And when I say the same would be true,</p> <p>10 that means you were not able to calculate a rate</p> <p>11 of heavy metal contamination of any of the talcum</p> <p>12 powder products in the studies you reviewed?</p> <p>13 MS. O'DELL:</p> <p>14 Objection. Vague.</p> <p>15 A I was not asked to.</p> <p>16 MS. BROWN:</p> <p>17 Q Did you attempt to quantify the amount</p> <p>18 of heavy metals?</p> <p>19 MS. O'DELL:</p> <p>20 Objection.</p> <p>21 A I certainly reviewed the literature to</p> <p>22 understand what information was available</p> <p>23 regarding the products that may have been used</p> <p>24 and what testing may have been done on</p>

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<p style="text-align: right;">Page 134</p> <p>1 those -- on those products. 2 MS. BROWN: 3 Q And, as it relates to fragrances, have 4 you calculated the amount of fragrances that are 5 present in Johnson & Johnson's baby powder 6 products? 7 MS. O'DELL: 8 Objection to form. 9 A I -- I wasn't asked to -- to make those 10 calculations. And I would defer to other expert 11 reports that I had an opportunity to review 12 recently that did perform those calculations. 13 MS. BROWN: 14 Q Your opinions in this case are not 15 dependent on whether or not -- 16 A I think that was -- 17 Q -- there are fragrances in 18 Johnson & Johnson's baby powder; correct? 19 MS. O'DELL: 20 Objection. 21 A Sorry. Let me read that. 22 Sorry. Could you rephrase your 23 question? The question that appears on the 24 monitor is that there are fragrances in</p>	<p style="text-align: right;">Page 136</p> <p>1 fragrances as well as asbestos, I would say my 2 opinion now is that that information continues to 3 support the biologically plausible mechanism 4 presented in my report. 5 MS. BROWN: 6 Q Your opinion that chronic inflammation 7 is a biologically plausible mechanism by which 8 talcum powder could cause ovarian cancer is not 9 dependent on heavy metals being present in talcum 10 powder; correct? 11 MS. O'DELL: 12 Object to the form. Asked and 13 answered. 14 A My -- my opinions are not based on -- 15 on any singular component or constituent because 16 the -- the available information did not 17 scientifically test any singular components 18 or -- or allow -- 19 I'm not aware of any studies that 20 examine the inflammatory or other effects of 21 talcum powder that contained heavy metals versus 22 did not. 23 MS. BROWN: 24 Q So, for purposes of your opinions in</p>
<p style="text-align: right;">Page 135</p> <p>1 Johnson & Johnson baby powder, question mark. 2 MS. BROWN: 3 Q That's why it's tricky when you read 4 the realtime. Just listen to my question. It'll 5 be more helpful. 6 Your opinion in this case is not 7 dependent on whether or not there are fragrances 8 in Johnson & Johnson baby powder. Correct? 9 MS. O'DELL: 10 Excuse me. Objection to form. 11 You may refer to realtime any time you 12 want to, Doctor. 13 But I object to the form of the 14 question. 15 A So my -- my -- I was -- what was 16 requested of me, again, stating for clarity, was 17 to describe a biologically plausible mechanism 18 for talc and all of its constituent components 19 having a role in inflammation and progression to 20 ovarian cancer based on -- on the information at 21 hand. 22 Certainly the fact, as we've been 23 provided later, the ex- -- the recent review of 24 some other expert reports regarding the</p>	<p style="text-align: right;">Page 137</p> <p>1 this case, for your piece of the puzzle, so to 2 speak, it is not important to you whether or not 3 there are heavy metals in baby powder; correct? 4 MS. O'DELL: 5 Objection to form. Asked and answered. 6 A No, that's not correct. I would say 7 the presence of all of the constituent components 8 is very important for -- from the -- from the 9 perspective of that biologically plausible 10 mechanism, and that includes the type of talc, 11 the structure of the talc, you know, its -- any 12 potential contaminants that are there, as well as 13 the complete spectrum of other constituent 14 components, fragrances, heavy metals. 15 And, of course, fragrances have their 16 own milieu of constituent components that, again, 17 I was not asked to comment on or describe in 18 detail but certainly are part of the overall 19 studies. 20 MS. BROWN: 21 Q You have a conclusion in your report on 22 page 17, Doctor, conclusion number 2, that talcum 23 powder products cause chronic inflammation. 24 Do you see that?</p>

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<p style="text-align: right;">Page 138</p> <p>1 A Yes.</p> <p>2 And I would -- and then my conclu- --</p> <p>3 Q Hold on. No question yet.</p> <p>4 A Okay.</p> <p>5 Q And what I want to know, Doctor, is how</p> <p>6 do you define the talcum powder products that</p> <p>7 you've listed here on page 17 of your report?</p> <p>8 A Primarily the products that are -- when</p> <p>9 I consider the totality of everything that I've</p> <p>10 been examining, the talcum powder products,</p> <p>11 including Johnson & Johnson and Shower to Shower</p> <p>12 as, you know, I refer to those consumer products</p> <p>13 under the term "talcum powder."</p> <p>14 Q What about other consumer talcum powder</p> <p>15 products? Are they included in your conclusions</p> <p>16 here on page 17?</p> <p>17 MS. O'DELL:</p> <p>18 Object to the form.</p> <p>19 A So my -- my conclusions are based on</p> <p>20 the -- on the literature review. And, similar to</p> <p>21 our discussions regarding contaminants and the</p> <p>22 ability to quantitate those, many of the studies</p> <p>23 did not specifically delineate which product or</p> <p>24 the timing of that product.</p>	<p style="text-align: right;">Page 140</p> <p>1 don't know if any of the studies used -- used</p> <p>2 that. I'd have to, again, would have to review</p> <p>3 some of that information to determine if there</p> <p>4 was a -- if that was a variable in any of the</p> <p>5 given studies that are the basis of the report.</p> <p>6 Q What methodology did you employ here in</p> <p>7 coming to your conclusion that chronic</p> <p>8 inflammation is caused by talcum powder products?</p> <p>9 MS. O'DELL:</p> <p>10 Objection. Asked and answered.</p> <p>11 A Yeah. Again, to restate, similar to</p> <p>12 the earlier questions, the -- my methodology was</p> <p>13 based on standard methodology for establishing</p> <p>14 biological plausibility, which is a, in a</p> <p>15 summary, a review of the totality of the evidence</p> <p>16 and then a summary of that to establish if, based</p> <p>17 on established or -- or known or factual</p> <p>18 principles, is there a -- can -- can a mechanism</p> <p>19 described go from cause to effect in a -- again,</p> <p>20 in an evidence-supported biologically plausible</p> <p>21 manner.</p> <p>22 There's a few references I can provide</p> <p>23 you that describe that method in a published</p> <p>24 manner, if that's helpful.</p>
<p style="text-align: right;">Page 139</p> <p>1 In contrast, some of the more recent</p> <p>2 information available specific to the</p> <p>3 constituents did meet that definition, so I would</p> <p>4 say these conclusions apply to both the specific</p> <p>5 products that I mentioned, Johnson & Johnson and</p> <p>6 Shower to Shower, as well as potentially other</p> <p>7 products. But quant- -- quantifying which study,</p> <p>8 I would have to go through study by study to</p> <p>9 answer any questions about which specific may be</p> <p>10 included.</p> <p>11 MS. BROWN:</p> <p>12 Q Do you include talc-containing</p> <p>13 deodorizing sprays in your definition of a talcum</p> <p>14 powder product?</p> <p>15 A None of the literature that -- that I</p> <p>16 reviewed or can recall was limited to those</p> <p>17 deodorant sprays in terms of a -- as a study</p> <p>18 variable that I can -- that I can think of.</p> <p>19 Q I'm not sure what you mean by that.</p> <p>20 A So the -- the basis of this report was</p> <p>21 on the talcum powder products, and I don't recall</p> <p>22 any of the studies that delineated talcum powder</p> <p>23 as a powder versus a talc-containing deodorant</p> <p>24 spray as a -- as a variable in the study. So I</p>	<p style="text-align: right;">Page 141</p> <p>1 MS. BROWN:</p> <p>2 Q That would be helpful.</p> <p>3 A They are -- these are our --</p> <p>4 MS. O'DELL:</p> <p>5 These are mine.</p> <p>6 THE WITNESS:</p> <p>7 Yeah.</p> <p>8 There's a -- I can get them --</p> <p>9 MS. BROWN:</p> <p>10 Q Are the published methods referenced in</p> <p>11 your report, Doctor?</p> <p>12 A No, actually, those are not.</p> <p>13 Q Okay. How would you go about finding</p> <p>14 the published methods that contain a description</p> <p>15 of the methodology you employed in this case?</p> <p>16 A No. It's that I was just saying that</p> <p>17 there's a published -- peer-reviewed published</p> <p>18 article that is the same as the method I used, if</p> <p>19 you -- if you wanted to review that. I didn't</p> <p>20 reference this specific paper in the report.</p> <p>21 Q Okay. And you have a -- do you have a</p> <p>22 copy of that in front of you right now, Doctor?</p> <p>23 A I do.</p> <p>24 Q Okay. So let's mark that as Exhibit</p>

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<p style="text-align: right;">Page 142</p> <p>1 14. 2 (DEPOSITION EXHIBIT NUMBER 14 3 WAS MARKED FOR IDENTIFICATION.) 4 MS. BROWN: 5 Q The title of the document is 6 "Evaluating Biological Plausibility in Supporting 7 Evidence For Action Through Systematic Reviews in 8 Public Health." 9 When is the first time you reviewed 10 this document, Doctor? 11 A In the last -- the last day or so. 12 Q Was the document provided to you by the 13 lawyers for plaintiffs? 14 A Yes. 15 Q The document is not referenced in your 16 report. True? 17 A It is not referenced. That's correct. 18 Q You did not review the document prior 19 to writing your report; correct? 20 A That's right. 21 Q The document was something the lawyers 22 for plaintiffs gave you after you had already 23 written and authored your report; correct? 24 A That's correct. I provided that as an</p>	<p style="text-align: right;">Page 144</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A No, that's not true. 4 MS. BROWN: 5 Q The lawyers for plaintiffs found 6 Exhibit 14 in the scientific literature; correct? 7 A That's correct. 8 Q In reviewing the scientific literature, 9 did you pay attention to the articles that 10 classify different types of talcum powder 11 products? 12 MS. O'DELL: 13 Object to the form. 14 A Could you give a specific example, and 15 then I -- 16 I wouldn't be able to answer without 17 knowing. 18 MS. O'DELL: 19 Q Sure. 20 Do you understand that some of the talc 21 epidemiology separates use by type of talcum 22 powder product? 23 MS. O'DELL: 24 Objection to form.</p>
<p style="text-align: right;">Page 143</p> <p>1 example of the -- of a published example of the 2 methodology that I employed. 3 Q You didn't endeavor to research the 4 scientific literature to find a published -- 5 published example of your methodology, did you? 6 MS. O'DELL: 7 Objection to form. 8 A I -- it wasn't -- that wasn't what I 9 was -- I wasn't asked to reference the 10 methodology in my report. I was, again, asked to 11 provide an opinion on a biologically plausible 12 mechanism and then, since our discussion has 13 transferred to methodology, to be complete, I 14 wanted to provide an example of a published 15 version of the methodology that -- that is 16 similar to or at least describes in a summary or 17 really in that particular paper an exemplary 18 fashion of the criteria for biological 19 plausibility and the methods used therein. 20 MS. BROWN: 21 Q Exhibit 14 is the product of research 22 the lawyers for plaintiffs conducted on a 23 published article regarding your methodology. 24 True?</p>	<p style="text-align: right;">Page 145</p> <p>1 A Again, do you have a specific example 2 of one of the studies so I could -- so I'd be 3 able to accurately answer your question? 4 MS. BROWN: 5 Q Here's what I want to know. Did you 6 look at the studies that separated deodorizing 7 sprays from powder products from cornstarch, for 8 example? 9 A Certainly in my review I made as 10 comprehensive a review of available literature 11 as -- as possible. And, again, if you can name a 12 specific study or one of the references, I can 13 confirm if that was -- if that was part of 14 the -- my review of the epidemiology. 15 Q Do you hold the opinion that talcum 16 powder-containing deodorant sprays causes 17 inflammation? 18 MS. O'DELL: 19 Objection to form. Vague. 20 A So if the -- 21 Again, I was asked to provide an 22 opinion on the biologically plausible mechanism 23 regarding talc and talcum powder. So, 24 presumably, any product that contains talcum</p>

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<p style="text-align: right;">Page 146</p> <p>1 powder could possibly follow that same</p> <p>2 biologically plausible mechanism.</p> <p>3 MS. BROWN:</p> <p>4 Q Is there a certain amount of talcum</p> <p>5 powder that a product must contain to cause</p> <p>6 inflammation?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form.</p> <p>9 A That wasn't something I was asked</p> <p>10 to -- to quantify, similar to the discussions we</p> <p>11 had about metals, fragrances, and asbestos.</p> <p>12 MS. BROWN:</p> <p>13 Q In forming your opinion that talcum</p> <p>14 powder products cause inflammation, you have not</p> <p>15 attempted to quantify how much talcum powder is</p> <p>16 in those products; is that right?</p> <p>17 MS. O'DELL:</p> <p>18 Objection to form. Asked and answered.</p> <p>19 A So my -- my review included a number of</p> <p>20 studies that looked at exposure rates, and my</p> <p>21 review also included the review of some studies</p> <p>22 that did not include use frequency as well as use</p> <p>23 duration. And, so, both of those considerations</p> <p>24 in terms of my review of the epidemiology were</p>	<p style="text-align: right;">Page 148</p> <p>1 Objection to form. Vague.</p> <p>2 A My -- my opinions are based on the</p> <p>3 available scientific literature regarding the</p> <p>4 testing performed on talcum powder and talcum</p> <p>5 powder products.</p> <p>6 I -- in my review of those results, I</p> <p>7 did not see a specific enumeration of any one</p> <p>8 particular chemical composition that was -- had a</p> <p>9 greater or lesser cause or effect relationship.</p> <p>10 MS. BROWN:</p> <p>11 Q Do you know how much talcum powder is</p> <p>12 in the Shower to Shower product?</p> <p>13 A No. I wasn't -- I wasn't asked to</p> <p>14 quantify that, and I would defer to some of the</p> <p>15 other expert reports regarding the composition of</p> <p>16 those products.</p> <p>17 Q Do you include cornstarch as a talcum</p> <p>18 powder product?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A Cornstarch was included in some of the</p> <p>22 epidemiology studies, as you -- as you mentioned</p> <p>23 a moment ago.</p> <p>24 MS. BROWN:</p>
<p style="text-align: right;">Page 147</p> <p>1 undertaken, but I did not attempt to quantify</p> <p>2 those relationships specifically.</p> <p>3 MS. BROWN:</p> <p>4 Q Okay. So there's two different issues</p> <p>5 there that I want to ask you about. One, I want</p> <p>6 to talk to you about whether the talcum powder</p> <p>7 products you've described on page 17 of your</p> <p>8 report have a specific composition, in your mind.</p> <p>9 Okay?</p> <p>10 Two, I want to talk to you about what</p> <p>11 you were just answering, which is is there a</p> <p>12 specific amount of the product that you believe</p> <p>13 causes inflammation.</p> <p>14 Do you understand the difference?</p> <p>15 A I do.</p> <p>16 MS. O'DELL:</p> <p>17 Objection to form.</p> <p>18 MS. BROWN:</p> <p>19 Q Okay. So let's start, one, with the</p> <p>20 product. In forming the opinion that talcum</p> <p>21 powder products cause inflammation, is there a</p> <p>22 particular chemical composition that you are</p> <p>23 relying on?</p> <p>24 MS. O'DELL:</p>	<p style="text-align: right;">Page 149</p> <p>1 Q Do you consider cornstarch to be a</p> <p>2 talcum powder product that also causes</p> <p>3 inflammation?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A My -- my review of the literature</p> <p>7 doesn't -- I'm thinking through the available</p> <p>8 studies, and I don't recall which studies that</p> <p>9 may -- may have been a dependent variable in</p> <p>10 terms of the determination. So I -- I can't</p> <p>11 answer that. I -- I don't have the information</p> <p>12 to answer that accurately.</p> <p>13 MS. BROWN:</p> <p>14 Q So, sitting here today, you're not sure</p> <p>15 if cornstarch would be a talcum powder product</p> <p>16 that causes inflammation as you described on page</p> <p>17 17?</p> <p>18 MS. O'DELL:</p> <p>19 Objection.</p> <p>20 A No. So --</p> <p>21 MS. O'DELL:</p> <p>22 Misstates the testimony.</p> <p>23 But you may answer if you understand</p> <p>24 the question.</p>

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<p style="text-align: right;">Page 150</p> <p>1 A So corn -- cornstarch and -- and talcum 2 powder are -- are -- when I'm referring to talcum 3 powder and talcum powder products, cornstarch, as 4 a singular component -- or singular product, is 5 not included in that definition. 6 Now, whether products that contain talc 7 also contain cornstarch, I -- I'm not able to 8 say. 9 MS. BROWN: 10 Q Right. And so that's my question. 11 What about a product like Shower to Shower that 12 contains talc and cornstarch? How have 13 you -- what methodology have you employed to 14 arrive at the conclusion that the Shower to 15 Shower product causes inflammation? 16 MS. O'DELL: 17 Object to the form. 18 A So my -- what I was requested was to 19 write an opinion as to the, again, the 20 biologically plausible mechanism that exposure to 21 talc and its constituents can lead to 22 inflammation. 23 I wasn't asked to provide as to what 24 the minimum or maximum thresholds are of any</p>	<p style="text-align: right;">Page 152</p> <p>1 on knowledge of how much talcum powder is 2 actually in the product; correct? 3 MS. O'DELL: 4 Objection. Misstates his testimony. 5 A Again, not a -- it wasn't part of -- it 6 wasn't an opinion I was asked to provide. 7 The -- the only -- or, I should say, 8 a -- a study that looked at the -- summarizing 9 the epidemiology literature that I reviewed, some 10 of those studies had a duration and component as 11 far as general talcum powder and talcum powder 12 product use. 13 MS. BROWN: 14 Q And I want to -- 15 A I don't -- 16 MS. O'DELL: 17 Excuse me. Let him finish. 18 A I was -- I was going to say I don't 19 recall those quantitating the percentage of 20 talcum powder in a -- in a given product in the 21 study. 22 MS. BROWN: 23 Q Right. And, so, you're getting a 24 little into the second question, which I do want</p>
<p style="text-align: right;">Page 151</p> <p>1 product or of any component of that product or 2 constituent. 3 The information I was provided was the 4 analysis of products like Shower to Shower and 5 Johnson & Johnson's product, to evaluate the 6 spectrum of talc and asbestos contamination in 7 some of the constituent components, and then -- 8 and, therefore, develop an opinion as to 9 the -- whether or not that those products are 10 supported by the same mechanism that I developed 11 the opinion on, meaning they have the constituent 12 components to cause inflammation. 13 MS. BROWN: 14 Q You have not made a determination of a 15 particular amount of talcum powder that is 16 required to be in a product for it to cause 17 chronic inflammation; correct? 18 MS. O'DELL: 19 Object to the form. 20 A I wasn't asked to provide such an 21 opinion. 22 MS. BROWN: 23 Q Your opinion that talcum powder 24 products cause chronic inflammation is not based</p>	<p style="text-align: right;">Page 153</p> <p>1 to talk about, which is how much people are 2 exposed to. 3 But sticking with just what's in the 4 product, have you made a determination that there 5 is a threshold amount of talcum powder that is 6 required to be in a product before you can 7 conclude that that product will cause chronic 8 inflammation? 9 MS. O'DELL: 10 Objection to form. Asked and answered. 11 A I -- again, I wasn't asked to provide 12 that -- that threshold opinion. 13 MS. BROWN: 14 Q And understanding whether or not there 15 is a threshold of how much talcum powder has to 16 be in a product to cause inflammation is not 17 necessary for you to opine that talcum powder 18 products cause chronic inflammation? 19 MS. O'DELL: 20 Objection. Misstates his testimony. 21 A So my -- my use of the terminology 22 "talcum powder products" includes the product and 23 all of its constituent components, which would 24 be, as we earlier discussed, talcum powder,</p>

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<p style="text-align: right;">Page 154</p> <p>1 fragrances, and any contaminating substances, 2 such as asbestos or -- or heavy metals. 3 And, so, therefore, to -- to more -- to 4 answer -- to be able to answer your question 5 accurately, we would -- I think we would have to 6 have some discussions as to the type of talcum 7 powder and the level of exposure to be able to 8 answer that regarding my opinion in terms of 9 level. 10 You know, the -- to clarify, the -- 11 during this research and the -- and having the 12 opportunity to review much of the literature in 13 talcum powder, it's a -- it's a fascinating field 14 because it is similar to asbestos. It appears 15 that the diversity of products and the diversity 16 of talc sources are like having a thorn bush with 17 different size thorns, and, depending on the 18 constituent components, you know, those thorns 19 are bigger or smaller or otherwise. And -- but 20 my opinion is based on the fact that the presence 21 of any of those thorns is sufficient to cause 22 some inflammatory response. 23 MS. BROWN: 24 Q Does a talcum powder product with 10</p>	<p style="text-align: right;">Page 156</p> <p>1 exposure to inflammation to the initiation of 2 core progression of cancer. And that's -- that's 3 been the focus of my opinion. 4 MS. BROWN: 5 Q Have you attempted to quantify talc 6 exposure as it relates to individuals? 7 A No, I have not. 8 Again, my -- my opinions are primarily 9 limited to the -- to the biological mechanism. 10 Q Well, isn't that dependent, though, on 11 how much talc a person is exposed to? 12 MS. O'DELL: 13 Objection. 14 A No. Again, separating the -- so the 15 question of the mechanism is -- 16 Can an exposure result in a mechanism 17 is separate from how much of an exposure is 18 required to cause that mechanism. 19 MS. BROWN: 20 Q So you've identified two questions for 21 us. One, can exposure result in a mechanism. 22 Correct? 23 A (Nods affirmatively.) 24 Q And, two, how much of an exposure do</p>
<p style="text-align: right;">Page 155</p> <p>1 percent talc cause chronic inflammation, in your 2 view? 3 MS. O'DELL: 4 Object to the form. Incomplete 5 hypothetical. 6 A I -- I don't have the information to 7 answer that. 8 MS. BROWN: 9 Q Does a talcum powder product with 10 50 percent talc cause chronic inflammation, in 11 your view? 12 A Again, I don't have the information to 13 answer that. 14 MS. O'DELL: 15 Object to the form. 16 MS. BROWN: 17 Q Is it necessary for you to determine 18 the level of talc in a product before determining 19 that it can cause chronic inflammation? 20 MS. O'DELL: 21 Objection. Asked and answered. 22 A No. My -- my -- so my opinion was 23 asked to answer the question of can -- is there a 24 biologically plausible mechanism from talc</p>	<p style="text-align: right;">Page 157</p> <p>1 you need to produce a mechanism. Correct? 2 MS. O'DELL: 3 Objection to form. 4 A Correct. 5 MS. BROWN: 6 Q And, in this case, you have answered 7 question number one, can exposure to talc cause 8 chronic inflammation. Correct? 9 A So my -- yeah. My -- my report details 10 the -- that opinion regarding a biologically 11 plausible mechanism. 12 Q You have not, in this case, answered 13 question number two, which is how much exposure 14 to talc is needed to cause chronic inflammation. 15 Is that right? 16 MS. O'DELL: 17 Objection to form. 18 A I wasn't asked to provide such a 19 mechanism or such a -- such an opinion. 20 Part of my review included some of the 21 epidemiology studies that examine that question, 22 but I certainly would defer to the -- the number 23 of -- of epidemiologists who are -- who are 24 providing testimony in this case, rather than try</p>

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<p style="text-align: right;">Page 158</p> <p>1 and paraphrase or opine on their work. 2 MS. BROWN: 3 Q Do you believe -- 4 MS. O'DELL: 5 Excuse me. We've been going about an 6 hour and 15 minutes. I'd love to take a break in 7 the next two or three minutes and -- 8 MS. BROWN: 9 It will probably take me a little 10 longer than that, but I'm mindful of the time, 11 and I'll just finish this subject and take a 12 break -- 13 MS. O'DELL: 14 Well, Dr. Levy, would you like a break 15 now? 16 THE WITNESS: 17 I think we can finish this subject. 18 MS. BROWN: 19 Thank you. 20 THE WITNESS: 21 I -- I'd rather conclude it than break 22 it up. 23 MS. BROWN: 24 Q So, Doctor, as it relates to how much</p>	<p style="text-align: right;">Page 160</p> <p>1 epidemiology studies found that conclusion and, 2 as -- as reviewed in the report, you know, found 3 an increased risk with increasing -- increasing 4 exposure appears, with the current knowledge in 5 the literature, to increase risk. But my opinion 6 was not to further quantify or further describe 7 that. 8 MS. BROWN: 9 Q Many of the studies you looked at did 10 not show a dose response; correct? 11 MS. O'DELL: 12 Objection to form. 13 A The limitation of several of the 14 studies I reviewed was that they did not examine 15 a dose response, so that, therefore, the study 16 was unable -- unable to make that conclusion 17 because they didn't look. 18 MS. BROWN: 19 Q And some of the studies that did 20 attempt to look at duration and/or frequency did 21 not show a linear dose response. Correct? 22 A I would have to look at the specific 23 studies. But in -- in summary, studies that did 24 look at dose response, particularly more recent</p>
<p style="text-align: right;">Page 159</p> <p>1 talc is needed to cause inflammation that can 2 cause cancer, that wasn't what you were asked to 3 figure out in this case. Is that right? 4 MS. O'DELL: 5 Objection to form. 6 A No. Well, I -- I was -- I was asked to 7 provide a review of the literature in terms of 8 talc exposure and inflammation and, in that 9 review, identified a number of studies that 10 examined some relationships to dose. 11 But I -- as you -- as you see in my 12 conclusions, none of them speak to dose or 13 duration in terms of that -- of that mechanism. 14 MS. BROWN: 15 Q You are not offering an opinion in this 16 case, Doctor, that perineal use of talcum powder 17 exposes an individual to enough talc to cause 18 chronic inflammation than can cause cancer; 19 correct? 20 MS. O'DELL: 21 Objection to form. 22 A My review of studies that attempted to 23 answer that specific question found a -- or a 24 number of studies, both -- or a number of</p>	<p style="text-align: right;">Page 161</p> <p>1 studies with larger numbers of participants, the 2 meta-analysis studies, found a significant 3 relationship between duration of use as well as 4 frequency of use in terms of their -- their risk 5 ratios. 6 Q And you are not going to offer the 7 opinion in this case that a woman using Johnson's 8 Baby Powder products perineally is exposed to 9 enough talcum powder to cause chronic 10 inflammation that can cause cancer. True? 11 MS. O'DELL: 12 Object to the form. 13 A I -- I wasn't asked to -- to provide 14 that opinion. 15 MS. BROWN: 16 Q And so, as such, you haven't attempted 17 to quantify how much talcum powder, as used 18 perineally, might get to the ovary. Is that 19 fair? 20 A Again, wasn't -- wasn't asked. I was 21 able to review some of the literature that 22 is -- appears to be long -- longstanding, well 23 established over the last greater than 40 years 24 that show a clear -- and I believe the FDA</p>

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<p style="text-align: right;">Page 162</p> <p>1 statement is -- is describing it as inarguable --</p> <p>2 that talc can migrate either from perineal</p> <p>3 exposure or even from inhalation exposure and be</p> <p>4 found in the ovary.</p> <p>5 A quantitation of how much exposure is</p> <p>6 required for that migration to occur and -- or</p> <p>7 how many times of exposure that migration needs</p> <p>8 to occur, I think it's been a fairly wide</p> <p>9 diversity of -- of studies on that subject.</p> <p>10 And, so, based on that, I'm not able to</p> <p>11 offer an opinion as to a minimal or maximum dose</p> <p>12 required to get there, other than -- but,</p> <p>13 instead, state that there is enough evidence to</p> <p>14 say factually that migration through the -- or</p> <p>15 through at least two mechanisms of exposure, talc</p> <p>16 can be found in the ovary. And I would suggest</p> <p>17 that -- or I'm not aware of any study that</p> <p>18 quantitates that further.</p> <p>19 Q Is it essential to your opinion that</p> <p>20 talc causes chronic inflammation that can lead to</p> <p>21 ovarian cancer that some amount of talc be</p> <p>22 present in the actual ovary?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>	<p style="text-align: right;">Page 164</p> <p>1 talc has to reach the ovary for the chronic</p> <p>2 inflammation to occur. Is that right?</p> <p>3 MS. O'DELL:</p> <p>4 Objection.</p> <p>5 A Not -- specific to your question,</p> <p>6 chronic inflammation, no, not necessarily.</p> <p>7 MS. BROWN:</p> <p>8 Q Is it your opinion in this case,</p> <p>9 Doctor, that a woman can develop ovarian cancer</p> <p>10 from chronic inflammation from talc without any</p> <p>11 particle of talc ever reaching the ovary?</p> <p>12 MS. O'DELL:</p> <p>13 Objection to form.</p> <p>14 A No, I didn't -- I -- I certainly did</p> <p>15 not make that statement. And the --</p> <p>16 Again, restating the -- this summary of</p> <p>17 my -- my opinion, that the biologically plausible</p> <p>18 mechanism for talc exposure to inflammation to</p> <p>19 cellular damage and then potentially creating the</p> <p>20 correct environment is based on evidence showing</p> <p>21 talc exposure in the ovary.</p> <p>22 MS. BROWN:</p> <p>23 Q Okay. So critical to your opinion,</p> <p>24 then, some talc has to get to the ovary at some</p>
<p style="text-align: right;">Page 163</p> <p>1 A So my -- my -- my opinion regarding the</p> <p>2 biologically plausible mechanism, again, does not</p> <p>3 rely on duration of exposure or amount of</p> <p>4 exposure.</p> <p>5 So, therefore, I would -- I would</p> <p>6 answer your question directly that it would be</p> <p>7 no, it does not -- it would not necessarily</p> <p>8 require talc to be present at the ovary at any</p> <p>9 given time point for there to be the potential</p> <p>10 that she had some inflammatory injury due to talc</p> <p>11 exposure at a previous time.</p> <p>12 That would, of course, be two different</p> <p>13 questions, one being effect of exposure and</p> <p>14 second question being is there clearance of that</p> <p>15 exposure over time if use is discontinued.</p> <p>16 So that's, again, two different -- two</p> <p>17 very different scientific studies would be --</p> <p>18 would be necessary.</p> <p>19 MS. BROWN:</p> <p>20 Q And you have not undertaken either of</p> <p>21 those studies. Is that fair?</p> <p>22 A That's fair.</p> <p>23 Q And -- but essential to your theory,</p> <p>24 though, Doctor, at some point, some amount of</p>	<p style="text-align: right;">Page 165</p> <p>1 time; right?</p> <p>2 A Well, the -- again, the -- my opinion</p> <p>3 is not based on how talc migrates or -- or when</p> <p>4 it can migrate. It's simply based on the, again,</p> <p>5 that biological premise, that exposure to talc.</p> <p>6 So I wasn't asked to opine whether or</p> <p>7 not talc exposure in a neighboring tissue could</p> <p>8 cause enough of an inflammatory response to</p> <p>9 affect the ovary.</p> <p>10 So there is the, certainly, the</p> <p>11 uninvestigated secondary effects that perhaps</p> <p>12 talc did not -- is not necessary or -- and</p> <p>13 required to get to the ovary to cause that</p> <p>14 effect. I'm -- I'm just not aware of any studies</p> <p>15 that have made that delineation of talc exposure</p> <p>16 to neighboring or surrounding organs.</p> <p>17 There is limited or some suggestion</p> <p>18 regarding the inflammatory response related to</p> <p>19 talc exposure in the lung that suggests that any</p> <p>20 talc exposure causes an inflammatory response.</p> <p>21 Again, but I can't point you to evidence that</p> <p>22 would take that inflammatory response and tie it</p> <p>23 specifically to ovarian cancer.</p> <p>24 So, again, my answer is there is not</p>

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<p style="text-align: right;">Page 166</p> <p>1 enough evidence to -- to support nor refute that</p> <p>2 any talc exposure can lead to an increased risk</p> <p>3 of ovarian cancer. What I do know from my review</p> <p>4 of the literature is the studies that looked at</p> <p>5 that specific exposure --</p> <p>6 And, to be clear, none of the</p> <p>7 epidemiology studies in humans quantitated the</p> <p>8 amount of talc reaching the ovary. It was simply</p> <p>9 the exposure and the -- and the perineal use of</p> <p>10 talc. So I think any discussion about how much</p> <p>11 did it reach the ovary and how long was it in the</p> <p>12 ovary is all hypothetical.</p> <p>13 Q Why don't we go off the record and take</p> <p>14 a break.</p> <p>15 Thank you, Doctor.</p> <p>16 VIDEOGRAPHER:</p> <p>17 Going off the record. The time is</p> <p>18 11:51 a.m.</p> <p>19 (LUNCH RECESS.)</p> <p>20 VIDEOGRAPHER:</p> <p>21 We're back on the record. The time is</p> <p>22 12:52 p.m.</p> <p>23 MS. BROWN:</p> <p>24 Q Welcome back, Doctor.</p>	<p style="text-align: right;">Page 168</p> <p>1 by well-established biological facts?</p> <p>2 A I would say the -- that chronic</p> <p>3 inflammation as a component of causing ovarian</p> <p>4 cancer is well established by biologically</p> <p>5 plausible facts.</p> <p>6 Q And what are those facts?</p> <p>7 A I think a number of studies that</p> <p>8 include the, first, the -- that talc or talcum</p> <p>9 powder causes inflammation. These exist in a</p> <p>10 number of forms, including very recent -- recent</p> <p>11 research by Dr. Saed, as we were -- touched on a</p> <p>12 little bit earlier in the -- in his paper, as</p> <p>13 well as classical studies with talc pleurodesis</p> <p>14 where there's -- you know, the fundamentals of</p> <p>15 that treatment is the inflammatory response</p> <p>16 caused by talc.</p> <p>17 Q Uh-huh.</p> <p>18 A And, so, that would be the -- some of</p> <p>19 the -- two examples of where factual information</p> <p>20 or at least observations that are supportive</p> <p>21 of -- of that information, you know, being</p> <p>22 considered as a bio- -- part of a biologically</p> <p>23 plausible mechanism.</p> <p>24 Q You would agree, Doctor, that not all</p>
<p style="text-align: right;">Page 167</p> <p>1 You were asked in this case to assess</p> <p>2 whether perineal use of talcum powder products</p> <p>3 induces a biologically plausible mechanism or</p> <p>4 mechanisms that result in ovarian cancer.</p> <p>5 Correct?</p> <p>6 A Correct.</p> <p>7 Q And define for us, if you will,</p> <p>8 "biologically plausible mechanism" as you used it</p> <p>9 in that sentence.</p> <p>10 A Excuse me. A mechanism that is</p> <p>11 biologically plausible, I mean that it is</p> <p>12 supported by either well-established biological</p> <p>13 facts or supported by at least a single line of</p> <p>14 evidence in published literature -- you know,</p> <p>15 generally speaking, peer-reviewed literature but</p> <p>16 certainly not limited to that -- where when you</p> <p>17 take -- when you consider the totality of the</p> <p>18 mechanism, that, essentially, each of the steps</p> <p>19 makes sense and is -- is supported by -- through</p> <p>20 either direct or indirect observations.</p> <p>21 Q Okay. And, in this case, as it relates</p> <p>22 to talcum powder, do you believe that the</p> <p>23 biologically plausible mechanism of chronic</p> <p>24 inflammation causing ovarian cancer is supported</p>	<p style="text-align: right;">Page 169</p> <p>1 inflammation causes cancer; correct?</p> <p>2 A I would say inflammation is not</p> <p>3 singularly responsible for cancer. However, I</p> <p>4 would clarify that the progression from cellular</p> <p>5 transformation to malignant cancer, at least with</p> <p>6 our current understanding of cancer biology,</p> <p>7 appears to have an inflammatory requirement,</p> <p>8 meaning that all cases of chronic inflammation</p> <p>9 don't necessarily cause cancer. However, our</p> <p>10 understanding of malignant transformation appears</p> <p>11 to have, universally, an inflammatory component.</p> <p>12 Q Okay. You would agree, though, that</p> <p>13 not all types of inflammation that the body</p> <p>14 experiences is inflammation that will lead to</p> <p>15 cancer. Correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A So I would -- taking a step back</p> <p>19 and -- and -- or to orient us to some of the</p> <p>20 basis of my opinions and some statements on</p> <p>21 general cancer biology --</p> <p>22 MS. BROWN:</p> <p>23 Q Well, let's start with just the</p> <p>24 question, though, Doctor.</p>

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<p style="text-align: right;">Page 170</p> <p>1 A Okay.</p> <p>2 Q Okay. Let's just keep it to an answer</p> <p>3 to the question. And then if you need an</p> <p>4 opportunity to make another statement on the</p> <p>5 record, that's fine.</p> <p>6 MS. O'DELL:</p> <p>7 Excuse me. Just object to the</p> <p>8 direction of the witness.</p> <p>9 Dr. Levy, you can answer a question</p> <p>10 however you'd like.</p> <p>11 MS. BROWN:</p> <p>12 Q And, just to orient you, Doctor, what</p> <p>13 I'm after, the question was: Not all</p> <p>14 inflammation that takes place in the body is</p> <p>15 inflammation that leads to cancer; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A So that, yeah, it's really too general</p> <p>19 a question. So you're -- you're -- what you're</p> <p>20 asking is does all inflammation have the</p> <p>21 potential to have -- have a relationship to</p> <p>22 cancer, and the answer to that is -- is yes, it</p> <p>23 does.</p> <p>24 Now, does every inflammatory response</p>	<p style="text-align: right;">Page 172</p> <p>1 cause cancer. The -- you need a contribution of</p> <p>2 other factors. And what those factors are is --</p> <p>3 some are understood. Some are areas of active</p> <p>4 research.</p> <p>5 In the -- in the specific case of</p> <p>6 ovarian cancer, it does appear, given the</p> <p>7 late- -- given the observations about latency</p> <p>8 period, that some level of chronic inflammation</p> <p>9 appears to be critical, but there is no</p> <p>10 definition of it being required to then having</p> <p>11 acute inflammation, again, in summary, causing</p> <p>12 cellular damage and then chronic inflammation</p> <p>13 providing a -- a supportive environment for that</p> <p>14 transformation.</p> <p>15 And, again, I'm -- I'm generalizing,</p> <p>16 which, as we discussed earlier in the day, cancer</p> <p>17 is very complex, and so we have to be cautious</p> <p>18 with generalizations.</p> <p>19 Q Talc pleurodesis is a medical procedure</p> <p>20 by which talc is injected into the pleura;</p> <p>21 correct?</p> <p>22 A Correct.</p> <p>23 Q And it is done that purposefully to</p> <p>24 elicit an inflammatory response. Correct?</p>
<p style="text-align: right;">Page 171</p> <p>1 directly cause cancer? And that's a question</p> <p>2 that I would say would be reasonable to -- in</p> <p>3 layperson's terms, in terms of general</p> <p>4 inflammation, is unlikely.</p> <p>5 But there -- their distinction</p> <p>6 between -- is -- you know, stated simply, is</p> <p>7 inflammation is a -- by our current knowledge of</p> <p>8 cancer, is a necessary component of cancer</p> <p>9 progression. That does not equate to all</p> <p>10 inflammation causing cancer.</p> <p>11 MS. BROWN:</p> <p>12 Q Does acute inflammation cause cancer,</p> <p>13 in your mind, Doctor?</p> <p>14 A It is a component of the cancer</p> <p>15 progression process. And, so, in my -- to</p> <p>16 provide a simplistic distinction between them is</p> <p>17 a --</p> <p>18 Acute inflammation which results in</p> <p>19 either an inflammatory response or direct</p> <p>20 cellular insult or injury can be viewed as having</p> <p>21 a -- causing cellular damage that results</p> <p>22 in -- in cellular transformation.</p> <p>23 Now, that is not sufficient for that --</p> <p>24 for those transformed cells to then go on to</p>	<p style="text-align: right;">Page 173</p> <p>1 A That's correct.</p> <p>2 Q And have you looked in consid- --</p> <p>3 forming your opinions in this case at the body of</p> <p>4 epidemiology that has followed folks who received</p> <p>5 talc pleurodesis to see if they developed cancer?</p> <p>6 MS. O'DELL:</p> <p>7 Object.</p> <p>8 A Somewhat, yes.</p> <p>9 MS. BROWN:</p> <p>10 Q And are you familiar with the findings</p> <p>11 of those studies that talc, when injected</p> <p>12 directly into the pleura for the purpose of</p> <p>13 causing inflammation, had not caused cancer?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A I would disagree with your conclusions.</p> <p>17 And, in fact, the literature I reviewed has, I</p> <p>18 think, two fundamental concerns. One is the time</p> <p>19 period that these patients were followed post</p> <p>20 pleurodesis, and the other that there -- there</p> <p>21 have been at least one report, perhaps two -- I</p> <p>22 would have to review to make sure I'm speaking</p> <p>23 accurately -- where there was indeed a</p> <p>24 asbestos-like response in the formation of a</p>

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<p style="text-align: right;">Page 174</p> <p>1 mesothelioma-like event in the -- in the -- in 2 the pleural space following talc pleurodesis. 3 However, you know, taking a step back, 4 given the relative rarity of that as a procedure, 5 particularly today, I think drawing conclusions 6 from that as its -- as its relationship to cancer 7 would be difficult, but I -- I do think 8 fundamentally the -- my use of that as an example 9 was not necessarily to tie talc specifically to 10 cancer. It was more to state that it's well 11 established that platy talc individually as it -- 12 used in those procedures causes an inflammatory 13 response. And so, you know -- and that is the 14 primary reason I used or reviewed that literature 15 for that purpose. 16 MS. BROWN: 17 Q Is it your opinion, Doctor, that talc 18 pleurodesis leads to cancer? 19 MS. O'DELL: 20 Object to the form. 21 A It is my opinion that talc pleurodesis 22 creates an environment supportive of cancer. And 23 whether or not some number of individuals may 24 progress, could progress or have progressed to</p>	<p style="text-align: right;">Page 176</p> <p>1 mid-'80s to early '90s. I'd have to, again, have 2 to review that -- 3 I gave that specific example of a 4 patient or cohort of patients that were found to 5 have, again, asbestos-like effects in the lung 6 leading to, at least in a case or more than 7 perhaps more than one case, a mesothelioma-like 8 effect like we -- like I just mentioned. 9 But, again, to point you to the exact 10 reference, I'd have to review. 11 MS. BROWN: 12 Q Are you relying on that reference in 13 forming your opinions in this case? 14 A No. Specifically -- again, to restate 15 the -- my description of the pleurodesis process 16 was to support the early part of the biological 17 mechanism that talc causes inflammation. So 18 that -- and, so, in the lung as a tissue, that 19 progression to cancer is -- is -- I think is a -- 20 is a -- is a supportive observation to the -- to 21 my overall principle. But, again, it's a 22 separate -- separate exposure type, certainly a 23 very different dosing, potentially, and, again, a 24 very different patient, or the patient is a very</p>
<p style="text-align: right;">Page 175</p> <p>1 cancer is -- you know, is -- is of limited 2 knowledge right now. 3 MS. BROWN: 4 Q What scientific support do you have for 5 your opinion that talc pleurodesis creates an 6 environment supportive of cancer? 7 A Oh, just that it causes an inflammatory 8 response. And, as we've been discussing, there 9 is ample evidence surrounding the role of 10 inflammation in cancer. There's a -- you know, 11 in a number of both reference studies and I think 12 generally, I would -- I would state that it's a 13 generally accepted fact in cancer biology. 14 Q What scientific support do you have for 15 your opinion that talc pleurodesis patients later 16 can and do develop cancer? 17 MS. O'DELL: 18 Object to the form. Misstate his 19 testimony. 20 A I'd have to review my -- review some of 21 the literature. And I can take a look if we want 22 to pause for a moment. 23 But there was -- I recall one study 24 involving talc pleurodesis that was maybe</p>	<p style="text-align: right;">Page 177</p> <p>1 different individual in the sense that they 2 obviously have reasons for going through the talc 3 pleurodesis which are -- which are -- which are 4 potentially compounding to the overall phenotype. 5 Q Have you endeavored to quantify the 6 difference between exposure to talc from 7 pleurodesis versus perineal use of cosmetic 8 talcum powder products? 9 MS. O'DELL: 10 Object to the form. 11 A I have -- I have not attempted to 12 delineate those two simply from the perspective 13 that, again, to the biological mechanism, the 14 initial premise is talc causes inflammation. And 15 when I examined literature to look for evidence 16 of that historically, talc pleurodesis is one 17 example of inflammation. There's now others, and 18 there's, subsequent to that, there's been 19 a -- now a number of -- or, you know, probably 20 a -- 21 Dr. Saed is one example of a reasonably 22 comprehensive molecular study examining specific 23 inflammatory markers tied specifically to 24 cellular exposure to, in the case of that paper,</p>

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<p style="text-align: right;">Page 178</p> <p>1 specific products, you know, such as the Shower</p> <p>2 to Shower and the -- and baby powder.</p> <p>3 MS. BROWN:</p> <p>4 Q Do you believe the inflammation caused</p> <p>5 by talc pleurodesis is chronic inflammation that</p> <p>6 leads to cancer?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form. Asked and answered.</p> <p>9 A Again, I believe the inflammatory</p> <p>10 response to talc exposure, which would include</p> <p>11 talc pleurodesis, induces an inflammatory</p> <p>12 response that would be supportive of cancer</p> <p>13 development and/or progression.</p> <p>14 MS. BROWN:</p> <p>15 Q And what scientific literature other</p> <p>16 than the one study you just referenced for us do</p> <p>17 you rely on for your opinion that talc</p> <p>18 pleurodesis induces an inflammatory response that</p> <p>19 would be supportive of cancer development and/or</p> <p>20 progression?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A All my -- my opinion is based on</p> <p>24 connecting two basic concepts. Talc exposure</p>	<p style="text-align: right;">Page 180</p> <p>1 powder products cause chronic inflammation in</p> <p>2 your November 2018 report before having seen the</p> <p>3 Saed paper from 2018; correct?</p> <p>4 MS. O'DELL:</p> <p>5 Object -- object to the form.</p> <p>6 Misstates his testimony.</p> <p>7 A The -- so, as we discussed -- we</p> <p>8 discussed earlier, I had seen abstract</p> <p>9 information as well as earlier publication from</p> <p>10 Dr. Saed's group and that the current 2018 paper,</p> <p>11 while not necessary for the opinions described in</p> <p>12 the report, certainly support those opinions,</p> <p>13 given that it was a direct assessment of specific</p> <p>14 products, specific -- in specific doses applied</p> <p>15 to cellular material and then measurements for</p> <p>16 inflammation made directly on that material.</p> <p>17 So while that particular study was</p> <p>18 not --</p> <p>19 And, again, the -- the earlier studies</p> <p>20 that were used to inform the 2018 paper were</p> <p>21 certainly used in this report and referenced</p> <p>22 the --</p> <p>23 And I'm just recalling when. Or if</p> <p>24 we've refer- -- had the opportunity to reference</p>
<p style="text-align: right;">Page 179</p> <p>1 causes inflammation. Inflammation has a</p> <p>2 significant role in cancer development.</p> <p>3 And, so, as far as -- each of those is</p> <p>4 supported by individual -- individual studies,</p> <p>5 and -- and now -- as I mentioned, there are now</p> <p>6 studies that directly tie those together in</p> <p>7 observation.</p> <p>8 MS. BROWN:</p> <p>9 Q What is the scientific basis for your</p> <p>10 support that talc exposure causes the type of</p> <p>11 inflammation that has been linked to cancer?</p> <p>12 A The most recent is the Saed publication</p> <p>13 that we discussed and -- or at least has been</p> <p>14 mentioned. In that study, looking at -- there</p> <p>15 was a assessment and, in some cases, a</p> <p>16 quantitation of the specific molecular markers</p> <p>17 for inflammation that were induced, and many</p> <p>18 of -- some of those markers are shared with known</p> <p>19 markers for -- for cancer progression, such as</p> <p>20 CA 125, as well as others.</p> <p>21 Q Are you referring to Saed's 2018 paper,</p> <p>22 Dr. Levy?</p> <p>23 A Yes.</p> <p>24 Q And you formed the opinions that talcum</p>	<p style="text-align: right;">Page 181</p> <p>1 the --</p> <p>2 Yeah. So we reference primarily the</p> <p>3 abstracts and then, again, as well as some of the</p> <p>4 other Saed work, which is the foundation of the</p> <p>5 directed studies that are described in the</p> <p>6 Reproductive Sciences paper that is Exhibit 12.</p> <p>7 MS. BROWN:</p> <p>8 Q Do you know that Dr. Saed is a paid</p> <p>9 expert for the plaintiffs' lawyers in this</p> <p>10 litigation?</p> <p>11 A I am aware. Yes.</p> <p>12 Q Have you considered that fact in</p> <p>13 evaluating Dr. Saed's work?</p> <p>14 A I did.</p> <p>15 Q Other than Dr. Saed's work from 2017</p> <p>16 and 2018, what evidence are you relying on to</p> <p>17 support your opinion that talcum powder produces</p> <p>18 the type of inflammation that can lead to cancer?</p> <p>19 A There has been -- looking through</p> <p>20 the -- there's the Buz'Zard and Lau, 2007. We</p> <p>21 were discussing the Hamilton -- Hamilton paper in</p> <p>22 terms of immune response but then, more</p> <p>23 specifically, the NTP reference in 1993. And in</p> <p>24 those cases, that was either looking at increases</p>

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<p style="text-align: right;">Page 182</p> <p>1 in reactive oxygen species generation --</p> <p>2 THE COURT REPORTER:</p> <p>3 Wait a minute. You have to slow down</p> <p>4 when you read, please.</p> <p>5 MS. O'DELL:</p> <p>6 You may continue.</p> <p>7 A Just to -- before I left off, I think,</p> <p>8 in those mentioned references, the reactive</p> <p>9 oxygen species generation, increased cell</p> <p>10 proliferation, and the use of -- in the specific</p> <p>11 case of Buz'Zard and Lau, was looking at the</p> <p>12 transformation in human ovarian cancer cells that</p> <p>13 were treated with talcum powder -- sorry -- human</p> <p>14 ovarian cells treated with talcum powder.</p> <p>15 MS. BROWN:</p> <p>16 Q Other than Buz'Zard, Hamilton, and NTP,</p> <p>17 is there anything else that you are relying on to</p> <p>18 support your opinion that the inflammation caused</p> <p>19 by talcum powder is the type of inflammation that</p> <p>20 causes cancer?</p> <p>21 A So there's additional references</p> <p>22 mentioned in the report; Gates, Belot, Harper and</p> <p>23 Saed. And then, in addition to that, there was</p> <p>24 a --</p>	<p style="text-align: right;">Page 184</p> <p>1 the details, and I -- there -- I am aware</p> <p>2 of -- mentioned earlier the Woodruff or Woodford,</p> <p>3 the earlier 1971 paper where I couldn't remember</p> <p>4 the author, is one of the earliest studies that I</p> <p>5 came across that had -- it has an animal model</p> <p>6 study.</p> <p>7 MS. BROWN:</p> <p>8 Q Doctor, is it your testimony that --</p> <p>9 First of all, do you think it's -- that</p> <p>10 in opining that there is a biologically plausible</p> <p>11 mechanism by which talcum powder causes chronic</p> <p>12 inflammation that can cause ovarian cancer, is it</p> <p>13 necessary, in your mind, to be able to show in</p> <p>14 animals that talcum powder does just that?</p> <p>15 A That talcum powder causes inflammation?</p> <p>16 Q That causes ovarian cancer.</p> <p>17 A No, I don't -- I don't think that</p> <p>18 that's -- that's certainly not a requirement.</p> <p>19 And the reason I -- the reason I give that answer</p> <p>20 is -- is quite simple; that there is a wide</p> <p>21 diversity of animal model studies that have not</p> <p>22 been able to mimic specifically or correctly</p> <p>23 human cancer for both -- both from a detection</p> <p>24 and most often from a treatment perspective,</p>
<p style="text-align: right;">Page 183</p> <p>1 Make sure I'm referring to the right</p> <p>2 one.</p> <p>3 So those were the -- those were the</p> <p>4 primary references. And then, of course, there</p> <p>5 were supporting materials and other earlier-cited</p> <p>6 work.</p> <p>7 But for the opinion regarding the type</p> <p>8 of inflammation that is caused by exposure to</p> <p>9 talc and as far as its specific relationship to</p> <p>10 cancer, there's -- there's -- I would point to</p> <p>11 the, at least in the Saed work, the specific</p> <p>12 quantitation of a very well-known tumor marker,</p> <p>13 CA 125, also known as mucin-16 elevation in that</p> <p>14 work, and then, in the case of Gates, some of the</p> <p>15 fundamental glutathione S-transferase has been</p> <p>16 associated or has been observed as a higher risk.</p> <p>17 And, so, that would -- those would be</p> <p>18 some examples.</p> <p>19 Q Are you aware of any animal study,</p> <p>20 Dr. Levy, that shows the inflammation caused by</p> <p>21 talcum powder causing precancerous changes?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A I would have to review the -- a few of</p>	<p style="text-align: right;">Page 185</p> <p>1 meaning that, fundamentally, humans and most --</p> <p>2 or at least the animal systems used as -- in</p> <p>3 scientific modeling are different. Some of their</p> <p>4 differences are due to different pathways, and</p> <p>5 others of the differences are due to actually,</p> <p>6 you know, fundamental immune system differences.</p> <p>7 Q The Hamilton article that you</p> <p>8 identified for me, we marked earlier in the</p> <p>9 deposition as Exhibit 7. Do you recall that?</p> <p>10 MS. O'DELL:</p> <p>11 Counsel, would you mind just placing</p> <p>12 the exhibits by the witness so he can refer to</p> <p>13 them as he'd like, please.</p> <p>14 A Yes, I recall this.</p> <p>15 MS. BROWN:</p> <p>16 Q And you would agree with me, Doctor,</p> <p>17 that the Hamilton study that we discussed this</p> <p>18 morning concluded that there were no neoplastic</p> <p>19 changes in the animals that were injected with</p> <p>20 talcum powder; correct?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form. Asked and</p> <p>23 answered.</p> <p>24 A No. No, I -- I wouldn't agree.</p>

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<p style="text-align: right;">Page 186</p> <p>1 MS. BROWN: 2 Q What evidence in Hamilton, Doctor, are 3 you relying on to support your position that 4 Hamilton showed neoplastic changes in animals 5 injected with talc? 6 A Well, I'm not -- I'm not stating that 7 Hamilton specifically showed that. 8 What I'm stating is that -- that there 9 is a Hamilton study as an animal model system to 10 make the conclusion that, in this animal model 11 system, that talc or talcum powder does not -- or 12 that causes or does not cause ovarian cancer is 13 not -- it's -- it is -- it has limitations. 14 And, as we discussed a bit earlier, the 15 two limitations are the very limited time points 16 of the animals. And if we look at the relative 17 and observed time points that we know now, as far 18 as latency period, these are well short of 19 those -- of those periods, even by rat standards, 20 and then the number of treated animals is 21 relatively small at ten. So the... 22 Q Doctor, do you rely on the Hamilton 23 article to support your opinion that talcum 24 powder produces chronic inflammation that causes</p>	<p style="text-align: right;">Page 188</p> <p>1 Q So this article looked at talc that was 2 injected into animals and found no evidence of 3 changes that lead to cancer. Correct? 4 MS. O'DELL: 5 Objection to form. 6 A Over the time period that they -- that 7 the study was performed, they did -- they did 8 not -- they did not report, and, in fact, as you 9 said, their statements are "no evidence of 10 cellular atypia or mitotic activity." 11 MS. BROWN: 12 Q So in opining, as you do in this case, 13 that talcum powder can biologically induce 14 chronic inflammation that causes ovarian cancer, 15 what methodology did you employ to consider the 16 findings of the Hamilton article? 17 A Well, I considered the findings of the 18 Hamilton article, as -- as referenced in the 19 report, primarily showing that talc has an 20 inflammatory or an immune response. And that was 21 the primary inclusion of the -- of the Hamilton 22 paper. 23 Q Not all inflammatory or immune 24 responses lead to cancer; right?</p>
<p style="text-align: right;">Page 187</p> <p>1 ovarian cancer? 2 A No, I don't rely -- again, I don't rely 3 on any -- there's not a reliance on any singular 4 article. 5 Q Did not mean to suggest that, Doctor. 6 I asked you for the scientific support 7 that you have for the opinions you're giving in 8 this litigation, and one of the articles you 9 identified was the Hamilton article. Correct? 10 A Uh-huh. Yes. 11 Q And I -- and this Hamilton article, as 12 we discussed, at page 103, found no evidence of 13 neoplasm in the rats injected with talc. Right? 14 A They -- I -- I don't -- they did 15 not -- I don't recall seeing a description of 16 neoplasm in the Hamilton article. 17 Q Page 103, second column, begins with 18 "No evidence." 19 A "No evidence of cellular atypia." 20 Q Uh-huh. "And concludes that in no 21 ovary was there any evidence of frank neoplasia"; 22 right? 23 A Yes. That's what's written in the 24 paper.</p>	<p style="text-align: right;">Page 189</p> <p>1 MS. O'DELL: 2 Objection. Asked and answered. 3 A As -- as we discussed, not -- not all 4 inflammatory responses have been shown to 5 conclusively lead to cancer. And, so... 6 MS. BROWN: 7 Q And Hamilton does not support the 8 opinion that the type of inflammatory response 9 that talc causes is the type that causes cancer. 10 Fair enough? 11 MS. O'DELL: 12 Object to the form. 13 A No. I would say that's unfair. 14 Because, again, the limitation of the Hamilton 15 study at the time it was performed was -- is a 16 very short timeline. So there is -- it is an 17 incomplete study in the sense that there is 18 certainly the possibility that the first aspect 19 or the first event that we're -- that we've been 20 discussing in cancer biology, the cellular damage 21 to lead to transformation, could have occurred in 22 some of the rat tissues but had not progressed 23 enough or had -- or had taken hold enough to 24 cause or to have that be detected in this</p>

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<p>1 particular study performed in the early '80s.</p> <p>2 And, furthermore, rat -- the rat model</p> <p>3 for human cancer, since this study has been in</p> <p>4 other cases, has some limitations as it relates</p> <p>5 to how applicable it is to the human condition.</p> <p>6 MS. BROWN:</p> <p>7 Q The NTP study that you identified as</p> <p>8 supporting your opinion, Doctor, that also does</p> <p>9 not show evidence of neoplastic changes; is that</p> <p>10 right?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 Doctor, please feel free to refer to</p> <p>14 the study if you need to.</p> <p>15 A Yeah. I'll do that now.</p> <p>16 (DEPOSITION EXHIBIT NUMBER 15</p> <p>17 WAS MARKED FOR IDENTIFICATION.)</p> <p>18 MS. BROWN:</p> <p>19 Q Doctor, we'll mark as Exhibit 15 to</p> <p>20 your deposition the NTP study to which you were</p> <p>21 referring.</p> <p>22 A Uh-huh.</p> <p>23 Q And this study, as well, does not show</p> <p>24 evidence of neoplastic changes.</p>	<p>1 Q Did you review, Doctor, the --</p> <p>2 And -- and what about the findings of</p> <p>3 NTP support your opinion?</p> <p>4 A Well, first, the inflammatory response,</p> <p>5 given the evidence by the accumulation of</p> <p>6 macrophages, and then, secondly, that in the</p> <p>7 female rats, the incidences of alveolar and</p> <p>8 bronchial or adenoma, carcinoma, and adenoma in</p> <p>9 the 18-milligram-per-meter group were</p> <p>10 significantly greater than those of controls.</p> <p>11 Q So did you consider the FDA's findings</p> <p>12 as it relates to the evaluation of the NTP study?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form. Vague.</p> <p>15 A Which -- which FDA?</p> <p>16 MS. BROWN:</p> <p>17 Q Have you considered, in connection with</p> <p>18 this case, the FDA's response to the 2014</p> <p>19 citizens petition?</p> <p>20 A Yes. That's familiar. And if I recall</p> <p>21 correctly --</p> <p>22 Or do you have -- is that handy?</p> <p>23 Q We'll mark that as Exhibit 16, Doctor.</p> <p>24 (DEPOSITION EXHIBIT NUMBER 16</p>
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<p>1 MS. O'DELL:</p> <p>2 Object to the form.</p> <p>3 Do you have a copy for me?</p> <p>4 It's what number?</p> <p>5 MS. BROWN:</p> <p>6 Fifteen.</p> <p>7 A I think the -- the important</p> <p>8 distinction in this particular study is this was</p> <p>9 an aerosol-based -- based study. It certainly</p> <p>10 was longer than the Hamilton but was -- was not a</p> <p>11 study that mimics the perineal use of talc.</p> <p>12 MS. BROWN:</p> <p>13 Q And, so, as it relates to your opinion</p> <p>14 in this case, Doctor, that talc induces a chronic</p> <p>15 inflammation that can lead to ovarian cancer, the</p> <p>16 NTP study does not support that, does it?</p> <p>17 MS. O'DELL:</p> <p>18 Object to the form.</p> <p>19 A I would say the study does support my</p> <p>20 opinion regarding talc and its role in</p> <p>21 inflammation. And if we refer to page 6 within</p> <p>22 the first -- the first paragraph, beginning with</p> <p>23 "Accumulations of macrophages."</p> <p>24 MS. BROWN:</p>	<p>1 WAS MARKED FOR IDENTIFICATION.)</p> <p>2 MS. BROWN:</p> <p>3 Q The reason I want to talk to you about</p> <p>4 this is it contains a review of the NTP study we</p> <p>5 were just discussing.</p> <p>6 First of all, did you consider this</p> <p>7 document in connection with your opinions in this</p> <p>8 case?</p> <p>9 A Yes, this document's familiar.</p> <p>10 Q Okay. And do you recall that a cancer</p> <p>11 prevention coalition wrote the FDA requesting</p> <p>12 that a warning label be placed on talcum powder</p> <p>13 products?</p> <p>14 A Yes.</p> <p>15 Q And do you recall, as evidenced on</p> <p>16 page 1, the FDA reviewed the data as it related</p> <p>17 to that question?</p> <p>18 A I -- I recall that the FDA reviewed the</p> <p>19 data and determined that it was insufficient, and</p> <p>20 they did not identify any new compelling</p> <p>21 literature at the time. But this was in 2014.</p> <p>22 Q And the NTP --</p> <p>23 MS. O'DELL:</p> <p>24 Excuse me, counsel.</p>

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<p>1 Were you finished? If you're finished, 2 that's fine. I just didn't know if you completed 3 your -- 4 A I'm just reading. There was one 5 other -- I recall -- 6 MS. BROWN: 7 Q Doctor, the NTP study that you pointed 8 us to was from 1993. Is that right? 9 A I believe that's correct. 10 Q All right. And one of the things that 11 the FDA did in this letter of 2014 is reviewed 12 that study; correct? 13 A Yes. 14 Q And I'll direct you to page 3 of 7. 15 And what the FDA concluded was that the study 16 lacked convincing scientific support because of 17 serious flaws in its design and conduct. 18 Do you see that? 19 MS. O'DELL: 20 Where are you reading? Sorry. 21 MS. BROWN: 22 Page 3. Page 3. 23 MS. O'DELL: 24 Oh. Page 3. Sorry. I thought you</p>	<p>1 the FDA claimed serious flaws. 2 MS. BROWN: 3 Q At the bottom of page 3 -- 4 A I see. 5 Q -- the sentence that begins, "However, 6 this study lacks convincing scientific support 7 because of serious flaws in its design and 8 conduct -- and conduct." 9 Do you see that? 10 A I do. 11 Q And one of the things the FDA points to 12 is that the investigators used micronized talc 13 instead of consumer grade talc, resulting in the 14 experimental protocol not being reflective of 15 human exposure conditions in terms of particle 16 size. 17 Do you see that? 18 A I do. 19 Q Have you made a determination in this 20 case, sir, about the size of the particles in 21 talcum powder products? 22 A I -- I've not made that distinction. 23 And -- 24 Q There's --</p>
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<p>1 said page 2. I'm sorry. 2 MS. BROWN: 3 Q Do you see that, Doctor? 4 A Starting with -- 5 Q Bottom of page 3 -- 6 A -- under toxicology findings? 7 Q So, to orient us here, Doctor, you 8 pointed, as evidence of support of your opinions 9 in this case, to the NTP study. Right? 10 A Correct. 11 Q And the folks who wrote to the FDA 12 requesting a warning on talc, they, too, pointed 13 to that study; right? 14 A Yes. 15 Q All right. And, so, the FDA reviewed 16 that study and, in the letter denying the 17 citizens petition, included its critique of that 18 study; correct? 19 A Correct. 20 Q And one of the things the FDA concluded 21 was that the study had serious flaws. True? 22 MS. O'DELL: 23 Objection to form. 24 A I don't -- do you -- I don't see where</p>	<p>1 A And, furthermore, I think the -- 2 importantly, the -- the flaws that the FDA points 3 out are, you know, not in disagreement with 4 our -- with our discussions surrounding both the 5 inflammatory response and then some of the 6 results there. I don't -- I don't see as a 7 concern -- 8 In fact, the -- it appears the FDA does 9 not disagree with the observation of the evidence 10 of carcinogenic activity in the non-asbestiform 11 talc. I think they -- 12 I share -- 13 Q Let's focus back on the question, 14 Doctor. 15 MS. O'DELL: 16 Excuse me. Let him finish his answer. 17 He's not finished. 18 A So, the, you know, the serious flaws 19 were the, I think, in this case, the specific 20 inclusion of nonasbestos talc and use of 21 micronized talc instead of consumer grade. So I 22 think in that -- in that sense, it's not 23 surprising that it had a different -- perhaps a 24 different response than may be observed with</p>

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<p>1 consumer products or talc that have -- may have 2 contaminants, whether it be asbestos or other. 3 MS. BROWN: 4 Q Do you remember the question I asked, 5 Doctor? 6 A Perhaps it would be helpful to restate. 7 Q I think, probably. 8 I asked if you had made a determination 9 in this case about the size of the particles in 10 talcum powder products. 11 A I -- so as far -- a determination, no. 12 I would -- I would say I have had an opportunity 13 to, you know, review or become more educated in 14 the diversity of talc products and the 15 interesting geographic relationship to different 16 size particles and -- in the presence or absence 17 of asbestiform particles in talc, which was a, 18 you know, fascinating area to become educated in. 19 As far as examining that in each of the 20 individual studies, I certainly was able to pay 21 attention to earlier or later studies as it 22 applied to when there was a specific description 23 of the talc, such as in the NTP study where 24 there -- that was one of the few that had a</p>	<p>1 when -- when used in the perineum compared to 2 inhalation. 3 But I have not seen a study that tried 4 to distinguish that in terms of having an exposed 5 group who inhaled talc only and then looked for 6 evidence of the presence in the ovary. 7 Q Back to the FDA document we were 8 discussing, Doctor, the FDA's critique of the NTP 9 study continues on page 4, where the FDA 10 identifies that the investigators conceded they 11 have problems with the aerosol generation system 12 and that the study did not include positive and 13 negative dust controls. 14 Did you consider those critiques in 15 evaluating the NTP study in this case? 16 MS. O'DELL: 17 Object to the form. 18 A Well, I -- I certainly considered -- 19 you know, considered them in -- as -- as I would 20 consider any -- any other evidence or opinion 21 on -- on these relevant subjects. 22 MS. BROWN: 23 Q The FDA went on to conclude, Doctor, 24 that, in light of the shortcoming, a panel of</p>
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<p>1 specific determination. 2 But I was basing my opinions on the 3 general behavior, summarized behavior of talc 4 based on the available evidence. 5 Q In forming your opinions in this case, 6 Doctor, have you concluded that a particular 7 route of exposure is more likely when women are 8 using talcum powder products perineally? 9 MS. O'DELL: 10 Object to the form. 11 A Certainly it would seem logical that 12 the route of talc exposure would be related to 13 the area that the talc is used. 14 MS. BROWN: 15 Q As such, do you believe and have you 16 assumed for purposes in your -- of your opinions 17 in this case that talc more likely migrates from 18 the perineum to the ovaries, as opposed to talc 19 being inhaled and then traveling down to the 20 ovaries? 21 A The evidence I've seen would suggest 22 that that migration that you described from the 23 perineum through the vagina into the fallopian 24 tubes into the ovary is certainly far more likely</p>	<p>1 experts at the 1994 ISRTP/FDA workshop declared 2 that the 1993 NTP study has no relevance to human 3 risk. 4 Do you share that conclusion? 5 MS. O'DELL: 6 Object to the form. 7 A I do not. And I think, importantly, 8 you know, even there at the bottom of page 4, 9 their point number 4 saying a cogent biological 10 mechanism by which talc might lead to ovarian 11 cancer is lacking. 12 MS. BROWN: 13 Q Uh-huh. 14 A I believe, as we're discussing today, 15 subsequent research and subsequent studies 16 have -- and including my report, have helped 17 define that plausible biological mechanism 18 which -- by which talc may lead to ovarian 19 cancer. 20 Q In answering my question, Doctor, you 21 pointed to a different portion of the same page 22 we were discussing; correct? 23 A Correct. 24 Q And what you pointed to was the FDA's</p>

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<p>1 conclusion here in 2014 that a cogent biological</p> <p>2 mechanism by which talc might lead to ovarian</p> <p>3 cancer is lacking. Correct?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A I -- I would disagree in the general</p> <p>7 nature of your statement and clarify it by saying</p> <p>8 the FDA found a lack of that mechanism based on</p> <p>9 the submitted literature of the citizen petition.</p> <p>10 MS. BROWN:</p> <p>11 Q So do you understand, Doctor, in</p> <p>12 evaluating the FDA's response, that they, in</p> <p>13 fact, did their own investigation in addition to</p> <p>14 the literature that was provided to them at the</p> <p>15 time?</p> <p>16 MS. O'DELL:</p> <p>17 Objection. Misstates the record.</p> <p>18 A Well, my reading of it, it says</p> <p>19 they -- that their -- that the scientific</p> <p>20 literature considered was submitted in support of</p> <p>21 both citizen petitions. And...</p> <p>22 MS. BROWN:</p> <p>23 Q Are you finished, Doctor?</p> <p>24 A Yes. I was just looking to see if</p>	<p>1 A I -- I disagree with the -- or I -- I</p> <p>2 have found, based on a review of the literature,</p> <p>3 that there are now additional supporting studies</p> <p>4 that would -- that would refute some of these</p> <p>5 conclusions of -- by the FDA review.</p> <p>6 Q And explain to us, then, Doctor, what</p> <p>7 methodology you employed or what research you</p> <p>8 conducted to reach a conclusion different from</p> <p>9 the FDA's conclusion in 2014.</p> <p>10 A I think, similar to what the FDA</p> <p>11 described, my review is of the literature now,</p> <p>12 you know, through 2018, examining the available</p> <p>13 information regarding inflammatory response to</p> <p>14 talc and then talc exposure as it relates</p> <p>15 to -- to the initiation of progression of cancer.</p> <p>16 Q Dr. Leavy -- Dr. Levy, do you think</p> <p>17 that the FDA, in concluding, as they did in 2014,</p> <p>18 that a cogent biological mechanism by which talc</p> <p>19 might lead to ovarian cancer is lacking, do you</p> <p>20 think they were wrong at that time?</p> <p>21 A I would -- I -- I would say that they</p> <p>22 were incomplete at that time. And, in fact, you</p> <p>23 know, one of the --</p> <p>24 If we -- if we look at page 5 in the</p>
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<p>1 there was a notation about further --</p> <p>2 Q I'll direct you, Doctor, to page 4, the</p> <p>3 second full paragraph that begins "In addition,</p> <p>4 the FDA stated."</p> <p>5 "In addition, we reviewed relevant</p> <p>6 toxicity literature (consisting of 15 articles</p> <p>7 from 1980 to 2008) not cited in your petition to</p> <p>8 determine if there was additional support at this</p> <p>9 point in time for your suggested warning label."</p> <p>10 Do you see that?</p> <p>11 A I do.</p> <p>12 Q And, based on the FDA's review of all</p> <p>13 the literature that they investigated at the</p> <p>14 time, they concluded that a cogent biological</p> <p>15 mechanism by which talc might lead to ovarian</p> <p>16 cancer was lacking. Right?</p> <p>17 MS. O'DELL:</p> <p>18 Objection to form.</p> <p>19 MS. BROWN:</p> <p>20 Q That was their conclusion; correct?</p> <p>21 A Yes, as written, that was their -- that</p> <p>22 was the FDA's conclusion.</p> <p>23 Q And you, Dr. Levy, disagree with that</p> <p>24 conclusion; correct?</p>	<p>1 one, two -- third full paragraph beginning with</p> <p>2 "while there exists," where the FDA does agree</p> <p>3 about the -- that it's plausible that perineal</p> <p>4 talc and other particulates reach the endometrial</p> <p>5 cavity and -- and associated organs and may</p> <p>6 elicit a foreign-body-type reaction and</p> <p>7 inflammatory response that in some exposed women</p> <p>8 may progress to epithelial cancers. What they do</p> <p>9 state, "However, there has been no conclusive</p> <p>10 evidence to support causality."</p> <p>11 So I would suggest that this paragraph</p> <p>12 is in support of the biologically plausible</p> <p>13 mechanism that I included in the report and</p> <p>14 that -- and, as we've been discussing, I</p> <p>15 haven't -- we -- we've not been discussing a</p> <p>16 causal or a formal causal evaluation.</p> <p>17 Q What information did you rely on,</p> <p>18 Doctor, in reaching the conclusion that there is</p> <p>19 a biological mechanism that the FDA did not?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Misstates his</p> <p>22 testimony.</p> <p>23 A I'm stating that the -- as we</p> <p>24 discussed, as we've been discussing today, the --</p>

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<p style="text-align: right;">Page 206</p> <p>1 the response to talc -- the response to talc</p> <p>2 exposure as an inflammatory response is supported</p> <p>3 by a number of studies, including the NTP study,</p> <p>4 which, although the FDA had some concerns with,</p> <p>5 the FDA also made statements regarding the</p> <p>6 exposure to talc and other particulates having an</p> <p>7 inflammatory response and that some exposed</p> <p>8 women's may have progressed to epithelial</p> <p>9 cancers.</p> <p>10 So, again, they're -- I think</p> <p>11 they -- they're in agreement there. So even the</p> <p>12 concerns with the study withstanding, there's --</p> <p>13 there's -- there's -- I still -- I still think</p> <p>14 the FDA report is in support of the mechanism</p> <p>15 that we've been discussing.</p> <p>16 MS. BROWN:</p> <p>17 Q The FDA concludes that a cogent</p> <p>18 biological mechanism by which talc might lead to</p> <p>19 ovarian cancer is lacking, do they not?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to form. Asked and answered.</p> <p>22 A But I would al- -- I would say the FDA</p> <p>23 contr- -- perhaps contradicts itself later in the</p> <p>24 same document, stating that there is both an</p>	<p style="text-align: right;">Page 208</p> <p>1 studies on which you're relying?</p> <p>2 A Not -- not for the contents of the</p> <p>3 report. Not that I'm aware of. I think we've --</p> <p>4 we've already discussed some of the other</p> <p>5 references contained in the report</p> <p>6 below and -- or at least by mention and Gates.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 17</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q I'm gonna mark as Exhibit 17 to your</p> <p>11 deposition the Buz'Zard study that you mentioned</p> <p>12 a moment ago. Do you recall that?</p> <p>13 A Yes.</p> <p>14 Q Do you rely on the Buz'Zard study in</p> <p>15 supporting your view that chronic inflammation</p> <p>16 from talcum powder use can cause ovarian cancer?</p> <p>17 MS. O'DELL:</p> <p>18 17?</p> <p>19 MS. BROWN:</p> <p>20 Yes.</p> <p>21 A Sorry. Can you restate your question?</p> <p>22 It wasn't...</p> <p>23 MS. BROWN:</p> <p>24 Q Do you rely on what we've marked as</p>
<p style="text-align: right;">Page 207</p> <p>1 inflammatory response and that in some exposed</p> <p>2 women they may progress to epithelial cancer.</p> <p>3 MS. BROWN:</p> <p>4 Q Other than the Woodruff article,</p> <p>5 Doctor, are you aware of any other study in</p> <p>6 animals that shows inflammation leading to</p> <p>7 cancer?</p> <p>8 MS. O'DELL:</p> <p>9 Objection to form. Other than those</p> <p>10 he's mentioned?</p> <p>11 A Yeah. I -- I would have to -- that</p> <p>12 would -- that would require review of the</p> <p>13 literature to -- to speak generally to animal</p> <p>14 studies and inflammation leading to cancer.</p> <p>15 MS. BROWN:</p> <p>16 Q Let me rephrase.</p> <p>17 In terms of your opinion here that talc</p> <p>18 causes chronic inflammation that causes ovarian</p> <p>19 cancer, you identified the Hamilton study, the</p> <p>20 NTP study, and the Woodruff study as animal</p> <p>21 studies that support that view. True?</p> <p>22 A I identified those studies as</p> <p>23 supportive of my -- of my opinion, yes.</p> <p>24 Q Are you aware of any additional animal</p>	<p style="text-align: right;">Page 209</p> <p>1 Exhibit 17, the Buz'Zard study, to support your</p> <p>2 view that talcum powder causes chronic</p> <p>3 inflammation that leads to ovarian cancer?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A As we've discussed, not singularly, but</p> <p>7 the -- as part -- as part of a complete picture</p> <p>8 of talc causing reactive oxygen species</p> <p>9 generation and other inflammatory responses,</p> <p>10 certainly this is a study that supports that</p> <p>11 opinion.</p> <p>12 MS. BROWN:</p> <p>13 Q Did you consider the type of cells that</p> <p>14 were evaluated in the Buz'Zard study?</p> <p>15 MS. O'DELL:</p> <p>16 Objection to form. Vague.</p> <p>17 A Certainly in terms of the overall</p> <p>18 experimental design.</p> <p>19 MS. BROWN:</p> <p>20 Q Did those -- were those normal human</p> <p>21 ovarian cells?</p> <p>22 A The -- the author has labeled them as</p> <p>23 normal human ovarian cells. But the -- you know,</p> <p>24 one of the key characteristics and similar to our</p>

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<p>1 comments on -- on animal systems is all -- all</p> <p>2 in vitro or in vivo studies that are using cell</p> <p>3 lines or animals have limitations. And in this</p> <p>4 case, you know, cell lines are particularly</p> <p>5 notorious in research in general for</p> <p>6 their -- for -- having to use care in extending</p> <p>7 findings to, you know, broad mechanisms in a --</p> <p>8 in a complex organism or in the human body.</p> <p>9 Q Sure.</p> <p>10 What you're -- what you're saying is</p> <p>11 you've got to be careful taking the findings from</p> <p>12 one cell study and extrapolating that to humans.</p> <p>13 Fair?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A The -- I think you have to be careful</p> <p>17 in evaluating each study in using the relevant</p> <p>18 components of that study and observations in that</p> <p>19 study as part of an overall mechanism and whether</p> <p>20 it's supportive or refutes such a mechanism.</p> <p>21 So --</p> <p>22 MS. BROWN:</p> <p>23 Q Did -- did you exercise that care here</p> <p>24 as it relates to the Buz'Zard study?</p>	<p>1 MS. O'DELL:</p> <p>2 Figure 3.</p> <p>3 A Figure 3?</p> <p>4 The one interesting observation in</p> <p>5 these two figures, both Figure 3A and Figure 3B,</p> <p>6 being the percentage of reactive oxygen specie</p> <p>7 generation in two different cell types, one in --</p> <p>8 one in Panel A and one in Panel B, is -- what I</p> <p>9 did not see included, if I --</p> <p>10 And I'm reading to see if I recall</p> <p>11 correctly.</p> <p>12 -- was a -- the -- the cell viability</p> <p>13 assay that they use for normalization has</p> <p>14 a -- somewhat of a limitation in that it -- it</p> <p>15 doesn't measure cell senescence. It only</p> <p>16 measures cell death. And, so, they -- not to</p> <p>17 dis- -- not that I disagree with your observation</p> <p>18 that it did not show the sig- -- significant</p> <p>19 increase, but there is the possibility that the</p> <p>20 reason that you see an actual decrease in the RS</p> <p>21 generation at the higher doses of talc is that</p> <p>22 cells have gone senescent and are essentially no</p> <p>23 longer responding to that increased dose.</p> <p>24 So I think there's at least two</p>
Page 211	Page 213
<p>1 A So the Buz'Zard study, you know,</p> <p>2 primarily, as -- as referenced, was to illustrate</p> <p>3 a study that showed an increase in reactive</p> <p>4 oxygen species generation, and that's the -- the</p> <p>5 primary purpose, or I should say primary</p> <p>6 observation on the -- from this.</p> <p>7 Now, certainly, the study contained</p> <p>8 more observations than that and certainly had</p> <p>9 some -- you know, a number of other components.</p> <p>10 Q How does the Buz'Zard study support</p> <p>11 your view that talcum powder causes chronic</p> <p>12 inflammation that causes ovarian cancer?</p> <p>13 A So the Buz'Zard study supports the view</p> <p>14 that exposure to talcum powder causes an</p> <p>15 inflammatory response.</p> <p>16 Q And that inflammatory response you saw</p> <p>17 in the Buz'Zard study does not increase with</p> <p>18 increasing doses of talcum powder. Correct?</p> <p>19 A I have to review. I believe that -- I</p> <p>20 believe their figures suggest --</p> <p>21 You know, are you referring</p> <p>22 specifically to their reaction -- reactive oxygen</p> <p>23 specie generation?</p> <p>24 Q Correct.</p>	<p>1 different ways to interpret some of these</p> <p>2 results. But I don't disagree with your</p> <p>3 observations regarding Figure 3.</p> <p>4 MS. BROWN:</p> <p>5 Q This study was conducted in a</p> <p>6 nutritional lab, not a cancer lab. True?</p> <p>7 A I'm -- I'm not aware of the type of</p> <p>8 laboratory or even the...</p> <p>9 Q And the study was -- the purpose of the</p> <p>10 study was to assess whether there was a certain</p> <p>11 effect of pine bark supplement? Is that right?</p> <p>12 MS. O'DELL:</p> <p>13 Objection to form.</p> <p>14 A They were looking at the -- the effect</p> <p>15 of a proprietary -- as stated by the authors, a</p> <p>16 proprietary mixture of water soluble</p> <p>17 bioflavonoids extracted from French maritime pine</p> <p>18 bark.</p> <p>19 MS. BROWN:</p> <p>20 Q Uh-huh.</p> <p>21 And did you investigate whether the</p> <p>22 ovarian cells that they used here were</p> <p>23 genetically altered?</p> <p>24 A No, I did not investigate that.</p>

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<p style="text-align: right;">Page 214</p> <p>1 Q Did you --</p> <p>2 I'm sorry. Were you done?</p> <p>3 A No. I would say it's fair -- it's fair</p> <p>4 to say that, you know, that the -- whether</p> <p>5 they're genetically altered or not, the -- the --</p> <p>6 you know, the same potential limitations as far</p> <p>7 as extrapolation to the human system would apply</p> <p>8 for any signs.</p> <p>9 But, again, the purpose of the Buz'Zard</p> <p>10 study, as -- as referenced in the report, was to</p> <p>11 indicate that there are studies that have shown</p> <p>12 an increase in reactive oxygen specie generation</p> <p>13 under exposure to -- to talc. And I think the</p> <p>14 study is reasonably clear on that increase</p> <p>15 relative to control.</p> <p>16 Q Except what this study showed, Doctor,</p> <p>17 is the more talc you give, the decrease from</p> <p>18 baseline in the reactive oxygen species.</p> <p>19 Correct?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Asked and</p> <p>22 answered. Misstates the testimony.</p> <p>23 MS. BROWN:</p> <p>24 Q Take a look at Figure 3; right, Doctor?</p>	<p style="text-align: right;">Page 216</p> <p>1 Q My question was, Doctor, what this</p> <p>2 study shows is the more talc you give, the less</p> <p>3 ROS generation there is. True?</p> <p>4 MS. O'DELL:</p> <p>5 Objection to form.</p> <p>6 A Again, under -- under the conditions of</p> <p>7 this particular study.</p> <p>8 MS. BROWN:</p> <p>9 Q Do you think the Buz'Zard study is</p> <p>10 scientifically reliable?</p> <p>11 A I have no basis to -- to suggest that</p> <p>12 it's -- that it's not reliable.</p> <p>13 Q Do you think that --</p> <p>14 A But I think there -- it does -- if</p> <p>15 there is a -- as we discussed earlier, an</p> <p>16 importance to not overgeneralize conclusions or</p> <p>17 lack of conclusions as, you know, outside of the</p> <p>18 system under study.</p> <p>19 Q If -- I want you to assume that the</p> <p>20 Buz'Zard study used genetically altered ovarian</p> <p>21 cells that did not have the p53 protein. Would</p> <p>22 that affect your analysis of Buz'Zard?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>
<p style="text-align: right;">Page 215</p> <p>1 A No. I agree. But, as stated, and an</p> <p>2 important clarification is whether that decrease</p> <p>3 is significant relative to the biology is -- is</p> <p>4 unknown.</p> <p>5 Q Right.</p> <p>6 This study certainly does not</p> <p>7 conclusively show that the more talc you give,</p> <p>8 the more ROS is generated. Correct?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A In these particular cell lines under</p> <p>12 these conditions, the -- the study certainly did</p> <p>13 not draw that conclusion.</p> <p>14 MS. BROWN:</p> <p>15 Q In fact, what this study shows is the</p> <p>16 more talc you give, the less of -- of ROS</p> <p>17 generation you have. Doesn't it?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I think importantly in this study, the</p> <p>21 time dependency for each of the doses is more</p> <p>22 important at the doses rather than comparing dose</p> <p>23 to dose.</p> <p>24 MS. BROWN:</p>	<p style="text-align: right;">Page 217</p> <p>1 A Well, that's -- that's an impossible</p> <p>2 question. Like you can't have --</p> <p>3 Well, you can't call a cell type a</p> <p>4 normal ovarian cell and -- absent p53 protein.</p> <p>5 You're -- it'd be -- you're fundamentally</p> <p>6 changing the biology of the cell as it relates to</p> <p>7 ovarian cancer or cancer in general.</p> <p>8 MS. BROWN:</p> <p>9 Q Because p53 is something that you have</p> <p>10 in your genes that prevents against ovarian</p> <p>11 cancer. True?</p> <p>12 MS. O'DELL:</p> <p>13 Objection.</p> <p>14 A So p5- -- p53 is a well-known, often</p> <p>15 mutated gene in a number of human cancers.</p> <p>16 MS. BROWN:</p> <p>17 Q And, so, if the ovarian cells that were</p> <p>18 studied in Buz'Zard did not have p53, it will</p> <p>19 call into question the study. Fair?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A It would be difficult to answer. From</p> <p>23 the perspective of the presence or absence</p> <p>24 of -- of p53 having an effect on the ability of a</p>

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<p style="text-align: right;">Page 218</p> <p>1 cell to generate reactive oxygen species under --</p> <p>2 under exposure to a substance like talcum powder</p> <p>3 would need to be tested directly.</p> <p>4 MS. BROWN:</p> <p>5 Q Fair to say, in your mind, a cell</p> <p>6 missing p53 is not a normal human ovarian cell.</p> <p>7 True?</p> <p>8 A That is true.</p> <p>9 (DEPOSITION EXHIBIT NUMBER 18</p> <p>10 WAS MARKED FOR IDENTIFICATION.)</p> <p>11 MS. BROWN:</p> <p>12 Q Handing you what we've marked as</p> <p>13 Exhibit 18 to your deposition, it's a review</p> <p>14 article titled "Perineal Talc Use and Ovarian</p> <p>15 Cancer," by Ross Penninkilampi.</p> <p>16 Do you see that?</p> <p>17 A I do.</p> <p>18 Q This is an article that you cited in</p> <p>19 your report; correct?</p> <p>20 A Correct.</p> <p>21 Q Does this article support your view</p> <p>22 that there is a biolo -- in part --</p> <p>23 Strike that.</p> <p>24 Does this article, in part, support</p>	<p style="text-align: right;">Page 220</p> <p>1 available literature and, in this case, review a</p> <p>2 meta-analysis of some reasonably large-scale</p> <p>3 studies to try to bring the proposed biologically</p> <p>4 plausible mechanism and include the -- the</p> <p>5 available epidemiological information for those,</p> <p>6 such as the Penninkilampi and Eslick paper we're</p> <p>7 discussing.</p> <p>8 Q What methodology did you employ in</p> <p>9 terms of reviewing the Penninkilampi findings as</p> <p>10 it relates to the question you addressed in your</p> <p>11 report?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A I -- I used the same methodology for</p> <p>15 the other studies as a review of the paper and</p> <p>16 its -- and its methods and conclusions.</p> <p>17 MS. BROWN:</p> <p>18 Q Do you believe this review, systematic</p> <p>19 review and meta-analysis, provides evidence that</p> <p>20 there's a biologically plausible mechanism by</p> <p>21 which talc can cause ovarian cancer?</p> <p>22 A Yes. It provided -- it shows an</p> <p>23 association between talc use and ovarian cancer.</p> <p>24 I don't -- I don't believe this particular study</p>
<p style="text-align: right;">Page 219</p> <p>1 your opinion in this case that there is a</p> <p>2 biologically plausible mechanism by which talcum</p> <p>3 powder can cause ovarian cancer which can</p> <p>4 cause --</p> <p>5 Strike that. Gonna do it again.</p> <p>6 Does this article support your view, in</p> <p>7 part, that talcum powder can cause chronic</p> <p>8 inflammation that can cause ovarian cancer?</p> <p>9 A This is an article I considered in</p> <p>10 the -- in the overall review and, in the</p> <p>11 conclusions of this article, found a -- an</p> <p>12 association between perineal talc use and ovarian</p> <p>13 cancer, according to the authors.</p> <p>14 So it was supportive of the proposed</p> <p>15 mechanism but was, again, in part.</p> <p>16 Q And, on page 13 and 14 of your report,</p> <p>17 you, in fact, reference the Penninkilampi study</p> <p>18 and some of its conclusions; correct?</p> <p>19 A Correct. On the -- on the bottom of</p> <p>20 page 13, yes.</p> <p>21 Q And what was the purpose of including</p> <p>22 this description of Penninkilampi in your expert</p> <p>23 report, Doctor?</p> <p>24 A Just to be sure to be -- to include</p>	<p style="text-align: right;">Page 221</p> <p>1 goes on to specifically elucidate causation, but</p> <p>2 it certainly shows the association.</p> <p>3 Q Well, the study specifically says that</p> <p>4 causation cannot be found, based on the results.</p> <p>5 Right?</p> <p>6 MS. O'DELL:</p> <p>7 Objection to form.</p> <p>8 MS. BROWN:</p> <p>9 Q If you look at page 42, Doctor, the</p> <p>10 very end of that first paragraph, "A certain</p> <p>11 causal link between talc use and ovarian cancer</p> <p>12 has not been established."</p> <p>13 Do you see that?</p> <p>14 MS. O'DELL:</p> <p>15 Where are you? Page 42. Where are you</p> <p>16 reading, please?</p> <p>17 MS. BROWN:</p> <p>18 Page 42, the end of the first</p> <p>19 paragraph.</p> <p>20 A Yes, I see that.</p> <p>21 MS. BROWN:</p> <p>22 Q Do you agree with that statement,</p> <p>23 Doctor, that a causal link between talc use and</p> <p>24 ovarian cancer has not yet been established?</p>

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<p>1 MS. O'DELL: 2 Objection. 3 A No, I wouldn't. But, again, my review 4 of this was to tie the biologically plausible 5 mechanism to, you know, human observation, not 6 provide a evaluation of the -- of the causal 7 link. 8 And I think the -- I would suspect that 9 the -- 10 I'm also not aware of a study that has 11 been able to -- or a -- or a -- what would be 12 necessary -- 13 I'm not aware of a study that has been 14 able to provide all of the recognized and 15 established methodology for causation and have 16 that applied in -- in talc. 17 MS. BROWN: 18 Q You're not aware of any study in the 19 talc epidemiology that has concluded that talcum 20 powder causes ovarian cancer; correct? 21 MS. O'DELL: 22 Objection to form. 23 A I'm aware of a number of studies that 24 have shown a strong correlation between the two.</p>	<p>1 examine that comprehensively, when you consider 2 the etiology of a disease and the latency periods 3 that have been observed in ovarian cancer in 4 general and the meta review by both this earlier 5 paper by Penninkilampi and then their subsequent 6 later work, you have a challenge of a -- in a 7 cohort study, a disease that is somewhat rare, 8 coupled with a exposure and latency period that's 9 been, in the -- in the limited number of studies 10 that have looked at this, appears to be quite 11 long, and then when you couple in the -- the 12 ethical concerns of actually performing a trial, 13 where it becomes a very difficult causation bar 14 to reach. 15 And, so, instead, we rely on the 16 case -- the available case-control data and then 17 systematic and meta-analysis reviews such as some 18 of the epidemiologists have performed to make 19 assessments into the likelihood that -- and the 20 strength of the association between talc use and 21 ovarian cancer. 22 Q Are you intending to provide an opinion 23 on the strength of the association between talc 24 use and ovarian cancer as evidenced in the</p>
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<p>1 But I would have to defer to the epidemiology 2 expert witnesses as to their opinion on 3 causation. 4 MS. BROWN: 5 Q One of the things you told us that you 6 reviewed in connection with your opinion was the 7 talc epidemiology. Is that right? 8 A That's right. 9 Q Did you conduct a review of all of the 10 available epidemiology on talcum powder use and 11 ovarian cancer? 12 A I certainly tried to review it as 13 comprehensively as -- as possible. 14 Q And, in connection with that review, 15 you'll agree there is not a single study that 16 concludes there is a causal association between 17 talcum powder use and ovarian cancer; correct? 18 MS. O'DELL: 19 Objection to form. 20 A So I would -- I would -- interestingly, 21 there -- it's -- it becomes a -- as more -- as 22 more and more information has become available 23 over the last few years, that becomes a more and 24 more difficult bar to meet, simply because, to</p>	<p>1 epidemiology? 2 MS. O'DELL: 3 Object to the form. 4 A No. My -- my opinions are limited to 5 the biologically plausible mechanism and then 6 examining whether that biologically plausible 7 mechanism presented is supported by observations 8 in -- in available human studies. 9 MS. BROWN: 10 Q And when you say your opinion is 11 limited to a biological plausible mechanism, are 12 you talking of the theoretical concept or are you 13 talking about in the context of women using 14 talcum powder perineally? 15 A In the context -- 16 MS. O'DELL: 17 Object to the form. 18 THE WITNESS: 19 Sorry. 20 MS. O'DELL: 21 Excuse me. 22 A In the -- in the context of women using 23 talcum powder perineally specifically, and 24 then -- and then certainly also the -- some of</p>

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<p style="text-align: right;">Page 226</p> <p>1 the fundamental aspects of that mechanism may</p> <p>2 apply to other exposures as well.</p> <p>3 MS. BROWN:</p> <p>4 Q Like what?</p> <p>5 A Well, the -- the other exposure we've</p> <p>6 been discussing, in -- in that some of the</p> <p>7 studies looked at inhalation exposure, et cetera.</p> <p>8 But the primary review and the primary</p> <p>9 opinion is based on the perineal use of talcum</p> <p>10 powder and that exposure that, as -- as we</p> <p>11 discussed earlier, has a -- certainly a strong</p> <p>12 association with perineal use and an exposure --</p> <p>13 exposure in the ovaries.</p> <p>14 Q Your opinion is that if a woman uses</p> <p>15 talcum powder perineally, there is a biologically</p> <p>16 plausible mechanism by which enough talcum powder</p> <p>17 can migrate from outside of her vagina to her</p> <p>18 ovary to cause chronic inflammation that can lead</p> <p>19 to ovarian cancer?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A So I'd say that the first part of your</p> <p>23 question is well established and included in the</p> <p>24 statements from FDA and others that that</p>	<p style="text-align: right;">Page 228</p> <p>1 trial that would examine that in a well-powered</p> <p>2 fashion to answer that question directly. And,</p> <p>3 certainly, as of today, there would be some</p> <p>4 significant ethical concerns with that design.</p> <p>5 So, instead, we rely on the cohort and</p> <p>6 case-control studies that are available. And</p> <p>7 those, again, studies are supporting an</p> <p>8 association between talc use and ovarian cancer.</p> <p>9 MS. BROWN:</p> <p>10 Q Right. But I'm talking about for your</p> <p>11 opinion that it's biologically plausible for</p> <p>12 perineal use of talc to cause ovarian cancer,</p> <p>13 have you made a determination, in your mind, of</p> <p>14 how long that perineal use has to take place for?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A I wasn't asked to provide -- to provide</p> <p>18 that opinion on -- and it -- on that length or</p> <p>19 exposure or duration.</p> <p>20 Again, it was -- the focus was on the</p> <p>21 biologically plausible mechanism that if you have</p> <p>22 a single exposure and that -- that that single</p> <p>23 exposure through to any other may be sufficient</p> <p>24 to trigger that mechanism.</p>
<p style="text-align: right;">Page 227</p> <p>1 migration does occur.</p> <p>2 And then the next step in the -- in the</p> <p>3 mechanism is that that causes inflammation which,</p> <p>4 again, as we've discussed, in a number of</p> <p>5 studies, that the inflammation occurs and then,</p> <p>6 in these human studies, in their systematic</p> <p>7 review, that there is a clear association or a --</p> <p>8 a observed association between perineal use of</p> <p>9 talc and the detection of ovarian cancer at some</p> <p>10 point in the -- in the women's lives and, in the</p> <p>11 case of the Penninkilampi, with a relationship to</p> <p>12 the number of lifetime applications.</p> <p>13 So considering those things together,</p> <p>14 yes, there is a biologically plausible mechanism</p> <p>15 for perineal talc use through to ovarian cancer.</p> <p>16 MS. BROWN:</p> <p>17 Q Have you -- is -- is your opinion that</p> <p>18 there's a biologically plausible mechanism</p> <p>19 dependent on a particular number of years of</p> <p>20 perineal use?</p> <p>21 MS. O'DELL:</p> <p>22 Objection to form.</p> <p>23 A The -- so the -- as we just discussed,</p> <p>24 there's no -- I can't point to a formal clinical</p>	<p style="text-align: right;">Page 229</p> <p>1 MS. BROWN:</p> <p>2 Q That's helpful, Doctor.</p> <p>3 So, as I understand your opinion, your</p> <p>4 piece of the puzzle here was to look at whether</p> <p>5 one single application of talcum powder to the</p> <p>6 perineum could lead to chronic inflammation that</p> <p>7 could cause ovarian cancer.</p> <p>8 MS. O'DELL:</p> <p>9 Objection.</p> <p>10 MS. BROWN:</p> <p>11 Q Correct?</p> <p>12 A No, no.</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form of the question.</p> <p>15 A No. That's not my -- my statement.</p> <p>16 My statement was that, based on the</p> <p>17 evidence available, that there's a biologically</p> <p>18 plausible mechanism for the -- for the cellular</p> <p>19 changes that -- that is independent of the</p> <p>20 exposure.</p> <p>21 MS. BROWN:</p> <p>22 Q You've made a determin- --</p> <p>23 A But certainly a single exposure would</p> <p>24 be the physically minimum number. And I</p>

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<p style="text-align: right;">Page 230</p> <p>1 believe -- I think we --</p> <p>2 Q That's what I want to understand. And</p> <p>3 how you -- how you make this biological</p> <p>4 plausibility determination is to evaluate a</p> <p>5 single exposure? Is that right?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A No.</p> <p>9 MS. O'DELL:</p> <p>10 Misstates his testimony.</p> <p>11 A That's -- that's not what I'm stating.</p> <p>12 My -- my statement is that the -- the</p> <p>13 biologically plausible mechanism is a mechanism</p> <p>14 that is independent of the exposure and that, as</p> <p>15 part of the description of that mechanism and the</p> <p>16 evaluation of the studies supporting that</p> <p>17 mechanism through an inflammatory response, the</p> <p>18 question of exposure, number, and duration,</p> <p>19 length of time, et cetera, would be a separate</p> <p>20 evaluation.</p> <p>21 MS. BROWN:</p> <p>22 Q Is your opinion that talcum powder</p> <p>23 products cause chronic inflammation that cause</p> <p>24 ovarian cancer limited to perineal use, or have</p>	<p style="text-align: right;">Page 232</p> <p>1 effect, it doesn't matter at all how much of the</p> <p>2 product is used?</p> <p>3 MS. O'DELL:</p> <p>4 Objection.</p> <p>5 MS. BROWN:</p> <p>6 Q Do you see what I'm struggling with?</p> <p>7 Can you help me understand? If I'm trying to</p> <p>8 figure out does X cause Y, it sounds like what</p> <p>9 you're saying is it doesn't matter how much X you</p> <p>10 have.</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A So we're -- we're talking about</p> <p>14 mech- -- so mechanistic action --</p> <p>15 MS. BROWN:</p> <p>16 Q Okay.</p> <p>17 A -- which means the -- you set aside the</p> <p>18 "how much." And the question is, from -- on a</p> <p>19 molecular level, can the presence of a particular</p> <p>20 compound in a particular location cause a</p> <p>21 biological effect. And, so, that is the primary</p> <p>22 focus of the opinion in the -- in the paper or --</p> <p>23 sorry -- in my report.</p> <p>24 And then extending that to how much,</p>
<p style="text-align: right;">Page 231</p> <p>1 you also evaluated body use of talcum powder</p> <p>2 products?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A My -- my focus was on the perineal use,</p> <p>6 and that's where the majority of the studies</p> <p>7 have -- have examined. So the focus was on</p> <p>8 perineal use of talcum powder.</p> <p>9 MS. BROWN:</p> <p>10 Q And in conducting that evaluation, the</p> <p>11 results of which are contained in your report,</p> <p>12 you did not endeavor to quantify how much talcum</p> <p>13 powder used perineally could possibly migrate to</p> <p>14 the ovaries; is that right?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form. Asked and answered</p> <p>17 maybe ten times already today.</p> <p>18 But you may answer the question.</p> <p>19 A Yeah. I -- I wasn't asked to -- to</p> <p>20 provide that opinion or attempt that</p> <p>21 quantitation.</p> <p>22 MS. BROWN:</p> <p>23 Q So when you conduct your analysis of</p> <p>24 whether something can biologically cause an</p>	<p style="text-align: right;">Page 233</p> <p>1 how long, and the dur- -- and then the intensity</p> <p>2 or duration of the biological effect, again, is a</p> <p>3 separate -- would be a separate discussion or</p> <p>4 separate study.</p> <p>5 So, again, to clarify, the focus had</p> <p>6 been on that -- some of the fundamental</p> <p>7 mechanisms, talc -- a talcum powder exposure to</p> <p>8 an inflammatory response to the inflammatory</p> <p>9 response causing cancer.</p> <p>10 Again, the -- I would refer to and</p> <p>11 defer to the other experts in epidemiology</p> <p>12 regarding their opinions on the validity of</p> <p>13 the asso- -- validity and strength of the</p> <p>14 associations, again, from a formal epidemiology</p> <p>15 perspective.</p> <p>16 My review of those studies has ind- --</p> <p>17 has relied on their conclusions, and, then, in my</p> <p>18 own review of their -- of their methodology</p> <p>19 showing a increasing association, that is the</p> <p>20 bookends of my -- of the mechanism I proposed.</p> <p>21 So what this study is looking at is</p> <p>22 perineal use of talc, getting cancer.</p> <p>23 The -- what I've proposed is in the</p> <p>24 middle. But this, again, the epidemiology</p>

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<p style="text-align: right;">Page 234</p> <p>1 studies are asking how many times, what, and 2 where, but there's been no evaluation that I'm 3 aware of that looks at exactly how the talc was 4 applied, when and where. Instead, it was asked 5 number of lifetime applications, duration of use, 6 and examining latency period. 7 And when I examine that information 8 from the perspective of that biological 9 mechanism, I, you know, notice some parallels in 10 between latency period averaging roughly twenty 11 years, which -- which mimics somewhat what's 12 observed in the asbestos field as far as, you 13 know, lung effect latency. 14 And then that continues into the 15 constituent -- or the other constituent 16 components of some of the products, including 17 testing into asbestos and some of the -- and 18 heavy metal exposure, et cetera, that those are, 19 again, supportive and offer a potential 20 amplifying effect in that -- in that mechanism, 21 given the nature of those other components. 22 Q What's the scientific support for the 23 amplification effect you just described? 24 A Just that the presence of</p>	<p style="text-align: right;">Page 236</p> <p>1 that opinion from the observations of a couple of 2 different studies, including the recent Saed 3 paper that did look at the specific consumer 4 product every -- you know, showing a -- if we do 5 it by way of comparison, between the Buz'Zard 6 paper and the recent Saed, seemingly a larger 7 magnitude of reactive oxygen species generation. 8 But, again, that is a -- extrapolating against 9 two different studies. 10 Q Do you -- 11 MS. O'DELL: 12 Excuse me. We've been going about an 13 hour and 20 minutes, maybe a little more. 14 MS. BROWN: 15 I think a little less. But I'm gonna 16 finish up. Then we'll take a quick break. 17 Q Does that work for you, Doctor? 18 I just want to finish Penninkilampi if 19 we can. 20 MS. O'DELL: 21 How much more do you have to go? 22 MS. BROWN: 23 About five or ten minutes. 24 MS. O'DELL:</p>
<p style="text-align: right;">Page 235</p> <p>1 more -- the -- 2 So if we extend beyond the opinion that 3 talc, as a com- -- as a singular compound, causes 4 inflammation and then also, based on the reviewed 5 expert reports, find that testing of talc has 6 been shown to contain asbestos or asbestos 7 fibers, that the presence of now two potential 8 insulting -- 9 I'm making a hypothesis or making a 10 statement that the -- you can have -- the more 11 biologically active compounds you have in an 12 exposure such as talc plus asbestos plus chromium 13 and then plus a milieu of chemicals that are in 14 fragrances may have an amplification effect on 15 that exposure and as part of that overall 16 biological mechanism. 17 Q Are you relying on a particular article 18 or any published scientific support for the 19 amplification argument? 20 MS. O'DELL: 21 Object to the form. He's answered the 22 question. 23 A No. I -- I don't know of a study that 24 is delineated. The -- it would be synthesizing</p>	<p style="text-align: right;">Page 237</p> <p>1 If you need a break, we can break now. 2 Or we can keep -- if you would like to wait five 3 or ten minutes, that's fine. Whatever's best for 4 you, Doctor. 5 THE WITNESS: 6 Yeah, if we could break now, that would 7 be great. 8 VIDEOGRAPHER: 9 Going off the record. The time is 10 2:10 p.m. 11 (OFF THE RECORD.) 12 VIDEOGRAPHER: 13 We're back on the record. The time is 14 2:26 p.m. 15 MS. BROWN: 16 Q Welcome back, Doctor. 17 Before we took a break, we were 18 discussing the Penninkilampi article. Do you 19 remember that? 20 A I do. 21 Q And one of the things the authors of 22 this very recent meta-analysis discussed is the 23 potential mechanism of ovarian cancer. Correct? 24 And I'll direct your attention to the</p>

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<p style="text-align: right;">Page 238</p> <p>1 discussion that begins on page 45. In the second</p> <p>2 sentence, the authors conclude here that the</p> <p>3 mechanism by which perineal talc use may increase</p> <p>4 the risk of ovarian cancer is uncertain.</p> <p>5 Do you see that?</p> <p>6 A I see that sentence, yes.</p> <p>7 Q And they go on to discuss the theory</p> <p>8 that talc could produce a chronic inflammatory</p> <p>9 response which could predispose to the</p> <p>10 development of ovarian cancer.</p> <p>11 Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Okay. And they go on to explain a</p> <p>14 little bit more about the theory. Do you see</p> <p>15 that?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A Specifically the sentence beginning</p> <p>19 with "it is argued"?</p> <p>20 MS. BROWN:</p> <p>21 Q Uh-huh. "It is argued that cellular</p> <p>22 injury, oxidative stress, and local increase in</p> <p>23 inflammatory mediators such as cytokines,</p> <p>24 prostaglandins may be mutagenic and, hence,</p>	<p style="text-align: right;">Page 240</p> <p>1 presence of the talc or a continued chronic</p> <p>2 immune response or chronic inflammatory response,</p> <p>3 again, either directly or indirectly related to</p> <p>4 the exposure, would help support a environment</p> <p>5 that would allow the cancer progression to occur.</p> <p>6 So that is simply delineating those --</p> <p>7 those two things as it relates to inflammation</p> <p>8 and talc exposure.</p> <p>9 Q So you described two potential</p> <p>10 responses to talc right now. Correct?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A At least two, yes.</p> <p>14 MS. BROWN:</p> <p>15 Q Okay. And one is an acute inflammatory</p> <p>16 response; correct?</p> <p>17 A Yes.</p> <p>18 Q And for that you point to the Saed data</p> <p>19 on reactive oxygen species; is that right?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to form.</p> <p>22 A That is one example, yes.</p> <p>23 MS. BROWN:</p> <p>24 Q Okay. Are there -- is there other</p>
<p style="text-align: right;">Page 239</p> <p>1 promote carcinogenesis."</p> <p>2 Do you see that?</p> <p>3 A I see that.</p> <p>4 Q This sentence refers to chronic</p> <p>5 inflammation promoting cancer. Correct?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A No. This -- this refers to that the</p> <p>9 presence of -- proposed that talc as a</p> <p>10 foreign -- that the presence of a foreign body</p> <p>11 would instigate a chronic inflammatory response.</p> <p>12 That's the statement in the paper.</p> <p>13 MS. BROWN:</p> <p>14 Q Is it your opinion that talcum powder</p> <p>15 can cause chronic inflammation that initiates</p> <p>16 cancer?</p> <p>17 A It's -- so it is -- it is my opinion</p> <p>18 is, part of the mechanism, that talcum powder can</p> <p>19 have two effects related to inflammation. The</p> <p>20 first effect is an acute effect resulting in</p> <p>21 cellular damage, and that is supported by the</p> <p>22 study showing increase in reactive oxygen species</p> <p>23 related to talc.</p> <p>24 The -- beyond that, the continued</p>	<p style="text-align: right;">Page 241</p> <p>1 scientific support for your opinion that talc can</p> <p>2 cause acute inflammation?</p> <p>3 A So it's any of the similar studies to</p> <p>4 Saed. And I would have to double-check the</p> <p>5 references, but they would have -- you know, any</p> <p>6 of the --</p> <p>7 MS. O'DELL:</p> <p>8 Feel free to --</p> <p>9 MS. BROWN:</p> <p>10 Q Buz'Zard?</p> <p>11 A So Buz'Zard would be one. Harper and</p> <p>12 Saed is -- is another.</p> <p>13 Q In your --</p> <p>14 A And so -- yeah. Yes, Buz'Zard and Lau</p> <p>15 and then -- yeah. So that would --</p> <p>16 Q Okay. So for your opinion that talc</p> <p>17 causes an acute inflamm- -- inflammatory</p> <p>18 response, you rely on the cell studies done by</p> <p>19 Saed and Buz'Zard; correct?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to the form.</p> <p>22 A Yes, among others.</p> <p>23 MS. BROWN:</p> <p>24 Q In your opinion, Doctor, does that</p>

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<p style="text-align: right;">Page 242</p> <p>1 acute inflammatory response resolve?</p> <p>2 A I don't -- I don't have any evidence to</p> <p>3 suggest it resolves or not. The --</p> <p>4 Again, getting back to the mechanism</p> <p>5 that has been -- that I've described and is</p> <p>6 supported by the literature we've been discussing</p> <p>7 is that there is a acute response as well as</p> <p>8 evidence for talc causing a more chronic</p> <p>9 inflammatory response. And so I've proposed a</p> <p>10 mechanism by which both of those can contribute</p> <p>11 to or enhance the development of cancer.</p> <p>12 Q Can both of those inflammatory</p> <p>13 responses that you just described initiate</p> <p>14 cancer?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form. Asked and</p> <p>17 answered.</p> <p>18 A They are certainly a component of that.</p> <p>19 And so, again, to restate the</p> <p>20 mechanism, the acute inflammatory response or</p> <p>21 the -- the formation of reactive oxygen species</p> <p>22 has been known for decades to cause cellular</p> <p>23 damage, and then cellular damage can result in</p> <p>24 mutation of -- of DNA.</p>	<p style="text-align: right;">Page 244</p> <p>1 they're not -- I don't have evidence to -- to</p> <p>2 delineate those specifically, other than -- other</p> <p>3 than the supported mechanism that an acute</p> <p>4 response can cause cellular damage, and then a</p> <p>5 chronic response can cause cellular damage and be</p> <p>6 supportive of that continued -- that continued</p> <p>7 transformation.</p> <p>8 So they are -- they -- those -- those</p> <p>9 two delineated immune responses can either work</p> <p>10 in -- in concert with each other, but there is no</p> <p>11 evidence to suggest that one is insufficient</p> <p>12 relative to the other in terms of progression of</p> <p>13 the disease.</p> <p>14 And I think specific to the -- to the</p> <p>15 supported mechanism is that there -- I'm not</p> <p>16 making that distinction in the -- in the report.</p> <p>17 MS. BROWN:</p> <p>18 Q Right. In your report, you don't talk</p> <p>19 about acute versus chronic inflammation.</p> <p>20 Correct?</p> <p>21 A That's correct. I don't delineate the</p> <p>22 two. Right.</p> <p>23 Q But, here today, as we discuss in more</p> <p>24 detail your opinions, you're explaining that</p>
<p style="text-align: right;">Page 243</p> <p>1 And then when you also consider the</p> <p>2 full constituents of the products, the potential</p> <p>3 presence --</p> <p>4 And this gets back to our earlier</p> <p>5 discussions about amplification.</p> <p>6 Components such as chromium, which have</p> <p>7 a direct DNA-damaging effect, can also</p> <p>8 ampli- -- again, add to the level of cellular</p> <p>9 damage present.</p> <p>10 And then the continued inflammatory</p> <p>11 response, whether it is a -- related to the</p> <p>12 initial acute response and a continuation of that</p> <p>13 or is a separate chronic inflammatory response</p> <p>14 would then support the environment necessary for</p> <p>15 the malignant transformation or the malignancy of</p> <p>16 the cancer to become what we -- what we would</p> <p>17 generally refer to as ovarian cancer.</p> <p>18 Q In your opinion, the chronic</p> <p>19 inflammation promotes the cancer but does not</p> <p>20 initiate it?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form. Asked and</p> <p>23 answered.</p> <p>24 A No. So I wouldn't -- I would say</p>	<p style="text-align: right;">Page 245</p> <p>1 you're -- in your mind, you see two potential</p> <p>2 inflammatory responses from talc. Right?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A I would disagree. I would say that</p> <p>6 I -- I -- based on the information and studies,</p> <p>7 the -- the review of other expert reports, that</p> <p>8 it presents a supported opinion that talc has an</p> <p>9 ability to cause an acute response as well as a</p> <p>10 chronic response.</p> <p>11 And, so, then, today we are discussing</p> <p>12 using that data in support of the -- of the</p> <p>13 mechanism as to how those -- those two responses</p> <p>14 can work together or separately in the</p> <p>15 progression of ovarian cancer.</p> <p>16 MS. BROWN:</p> <p>17 Q At the time you wrote your report in</p> <p>18 November of 2018, were you of the view that talc</p> <p>19 can cause both acute and chronic inflammatory</p> <p>20 response?</p> <p>21 A Yes. I mean, it was -- I was of the</p> <p>22 view it causes an inflammatory response. And</p> <p>23 then, as I continued to review information</p> <p>24 available, it became clear that the talc</p>

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<p style="text-align: right;">Page 246</p> <p>1 response, being an inflammatory response in</p> <p>2 totality, may have the ability to have</p> <p>3 those -- to -- to have two independent responses</p> <p>4 in tissues.</p> <p>5 Q And, in your opinion, can both the</p> <p>6 acute inflammatory response and the chronic</p> <p>7 inflammatory response separately cause ovarian</p> <p>8 cancer?</p> <p>9 A Under the -- the mechanism I've</p> <p>10 proposed, yes, that would be a -- a possibility</p> <p>11 that they could separately cause, given that</p> <p>12 they -- they're both inflammatory responses, they</p> <p>13 both cause cellular damage.</p> <p>14 And in the case -- in this case,</p> <p>15 delineating the acute from chronic was more to</p> <p>16 clarify the cellular damage aspect, the</p> <p>17 transformative aspect of cancer from the -- the</p> <p>18 necessary tumor progression aspects of cancer to</p> <p>19 actually progress to disease.</p> <p>20 Q In your opinion, Doctor, does talc</p> <p>21 always first cause an acute reaction and then a</p> <p>22 chronic reaction?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>	<p style="text-align: right;">Page 248</p> <p>1 important.</p> <p>2 Q So there is a length of time or an</p> <p>3 amount of exposure that would cause a chronic</p> <p>4 inflammation that is different from the length of</p> <p>5 time and the magnitude of exposure that will</p> <p>6 cause an acute inflammation?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form. Misstates his</p> <p>9 testimony.</p> <p>10 A Yeah, no. Not -- that's not what</p> <p>11 I -- that's not what I've stated.</p> <p>12 I've simply stated that if we -- if we</p> <p>13 look at the -- what is known about inflammation</p> <p>14 and the biological response to foreign bodies,</p> <p>15 you can have an initial acute response mediated</p> <p>16 by the immune system and mediated by some of the</p> <p>17 cellular damage that takes place, and then that</p> <p>18 same response may continue in a chronic form for</p> <p>19 some period of time and at some level of</p> <p>20 magnitude.</p> <p>21 Now, certainly there is likely a</p> <p>22 dependency or, I should say, likely a</p> <p>23 relationship to the amount of exposure and the</p> <p>24 magnitude of that response.</p>
<p style="text-align: right;">Page 247</p> <p>1 A I -- I -- I don't have evidence</p> <p>2 to -- to state that and would defer to some of</p> <p>3 the other expert witnesses, like Dr. Saed, for</p> <p>4 opinions on acute response versus chronic.</p> <p>5 MS. BROWN:</p> <p>6 Q In your opinion, though, you have at</p> <p>7 least delineated in your mind two different types</p> <p>8 of inflammatory responses. Correct?</p> <p>9 MS. O'DELL:</p> <p>10 Objection to form.</p> <p>11 A I've -- I have described two mechanisms</p> <p>12 for inflammation that -- that both can -- are</p> <p>13 both supportive of the overall mechanism that</p> <p>14 we're discussing.</p> <p>15 MS. BROWN:</p> <p>16 Q And is it -- is there a length of time</p> <p>17 that differentiates an acute inflammatory</p> <p>18 response from a chronic inflammatory response?</p> <p>19 A Certainly I would say there -- in my</p> <p>20 opinion, there would -- it would be a potential</p> <p>21 time dependency or a magnitude dependency to</p> <p>22 delineate an acute versus chronic response. But,</p> <p>23 again, for the purpose of the biological</p> <p>24 mechanism, separating them on those lines is not</p>	<p style="text-align: right;">Page 249</p> <p>1 But, again, the -- the opinions here</p> <p>2 are specific to the mechanism and the initial</p> <p>3 elucidation of that response and, you know,</p> <p>4 not -- not on a quantitation of a -- a</p> <p>5 dose-response relation -- or a dose-response</p> <p>6 curve or relationship.</p> <p>7 MS. BROWN:</p> <p>8 Q Do you believe that every time a talc</p> <p>9 particle enters the human body, it produces a</p> <p>10 inflammatory response?</p> <p>11 A All of the evidence would suggest yes.</p> <p>12 Q Have you considered Heller's 1996 study</p> <p>13 on that score?</p> <p>14 A I would have to --</p> <p>15 On the score of inflammatory response?</p> <p>16 Q Do you recall that Heller looked at</p> <p>17 benign ovarian tissue and identified the</p> <p>18 potential presence of talc?</p> <p>19 A Sounds familiar.</p> <p>20 Q I'll hand it to you.</p> <p>21 (DEPOSITION EXHIBIT NUMBER 19</p> <p>22 WAS MARKED FOR IDENTIFICATION.)</p> <p>23 MS. BROWN:</p> <p>24 Q Handing you, Doctor, what we've marked</p>

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<p>1 Heller's '96 article as Exhibit 19.</p> <p>2 And what I want to ask you about is</p> <p>3 Heller's finding as it relates to no reaction to</p> <p>4 the talc particle. Did you consider that --</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 MS. BROWN:</p> <p>8 Q -- in forming your opinion here?</p> <p>9 MS. O'DELL:</p> <p>10 Excuse me. Object to the form.</p> <p>11 MS. BROWN:</p> <p>12 Q I'll direct you, Doctor.</p> <p>13 On page 1508 of the Heller article,</p> <p>14 right above the comments section, "The</p> <p>15 investigators on this study concluded no evidence</p> <p>16 or response to talc, such as foreign body giant</p> <p>17 cell reactions or fibrosis in the tissue."</p> <p>18 My question is whether, in your</p> <p>19 opinion, every time talc is -- enters the body,</p> <p>20 it necessarily produces an inflammatory response.</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A No. My opinion is that every time talc</p> <p>24 enters the body, that has the potential to cause</p>	<p>1 mechanism that talc causes inflammation and then</p> <p>2 inflammation has a role in ovarian cancer.</p> <p>3 Extending that to circumstances where</p> <p>4 an exposure would not cause inflammation is -- is</p> <p>5 not germane to that -- to that mechanism and, in</p> <p>6 fact, again, not supported by literature to show</p> <p>7 that, you know, that a single exposure or some</p> <p>8 number of exposures are necessary or sufficient</p> <p>9 for a particular phenotype.</p> <p>10 MS. BROWN:</p> <p>11 Q So this Heller study purports to have</p> <p>12 found talc in ovarian tissue without an</p> <p>13 inflammatory response; right?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A In looking at their --</p> <p>17 Just one moment.</p> <p>18 So this was a --</p> <p>19 So is your -- is your question that</p> <p>20 the -- if the -- if the author showed talc being</p> <p>21 present in normal ovarian tissue?</p> <p>22 Q Well, first my question is did you</p> <p>23 consider this article in connection with your</p> <p>24 opinions in the case?</p>
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<p>1 an immune response.</p> <p>2 MS. BROWN:</p> <p>3 Q Have you made a determination about</p> <p>4 whether or not that always happens?</p> <p>5 A I'll have --</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form. It's vague.</p> <p>8 A I'm not aware of any --</p> <p>9 There -- there -- these -- none of the</p> <p>10 studies that have been reviewed have been</p> <p>11 designed to answer the question of "if ever."</p> <p>12 MS. BROWN:</p> <p>13 Q So, in your view, then, it's an open</p> <p>14 question about whether talc can be inside the</p> <p>15 body and not produce an inflammatory response.</p> <p>16 MS. O'DELL:</p> <p>17 Object.</p> <p>18 MS. BROWN:</p> <p>19 Q Is that fair?</p> <p>20 MS. O'DELL:</p> <p>21 Excuse me. Objection to form.</p> <p>22 Misstates his testimony.</p> <p>23 A So my -- my -- my testimony regarding</p> <p>24 the mechanism is that there is a well-supported</p>	<p>1 A I don't recall this article</p> <p>2 specifically, and I don't believe I cited it.</p> <p>3 I guess there's -- no.</p> <p>4 Q And then my second question, Doctor, is</p> <p>5 is it your opinion that every time the human body</p> <p>6 is exposed to particles of talc, it necessarily</p> <p>7 produces an inflammatory response that can either</p> <p>8 promote or initiate cancer of the ovaries?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A No. My --</p> <p>12 MS. O'DELL:</p> <p>13 Vague.</p> <p>14 A My comment was that the -- that any</p> <p>15 exposure to talc, particularly the perineal</p> <p>16 exposure to talc, has the potential to cause an</p> <p>17 inflammatory reaction.</p> <p>18 I don't have any evidence that all of</p> <p>19 the studies that we've been reviewing are in</p> <p>20 support -- are in support of that mechanism, but</p> <p>21 I don't know of a study that perhaps has been</p> <p>22 able to draw a conclusion, from a similar size</p> <p>23 study, to show that you can get significant talc</p> <p>24 accumulation without an inflammatory response.</p>

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<p>1 MS. BROWN:</p> <p>2 Q Do you think you need significant talc</p> <p>3 accumulation in the human body to cause or</p> <p>4 promote ovarian cancer?</p> <p>5 MS. O'DELL:</p> <p>6 Objection to form.</p> <p>7 A I wasn't asked to -- to provide --</p> <p>8 provide that opinion.</p> <p>9 And, again, referring to the studies</p> <p>10 that have -- that were reviewed and included in</p> <p>11 the report, there is a relationship between</p> <p>12 lifetime exposure and an increased risk in the</p> <p>13 epidemiology reports.</p> <p>14 But more detail on that in this</p> <p>15 discussion, I would defer to the epidemiology</p> <p>16 experts. But the -- there -- there does appear</p> <p>17 to be a -- more of a response based on more talc</p> <p>18 in the -- in the studies referenced.</p> <p>19 MS. BROWN:</p> <p>20 Q So on --</p> <p>21 Do you have any reason to dispute the</p> <p>22 findings of Heller here of talc in the ovaries</p> <p>23 without a foreign body reaction?</p> <p>24 MS. O'DELL:</p>	<p>1 A In -- in terms of cancer, the</p> <p>2 epidemiology would suggest -- or I would say</p> <p>3 the -- the evidence in the literature is -- does</p> <p>4 not allow that question to be answered, and the</p> <p>5 reason being is when you look at the latency of</p> <p>6 the disease and the progression of the disease</p> <p>7 and the challenges in detecting it, there just</p> <p>8 has not been enough time with the, perhaps, rigor</p> <p>9 of analysis that is undergoing now to make that</p> <p>10 assessment of is it 100 percent of the time or is</p> <p>11 it something less than 100 percent of the time.</p> <p>12 I think, statistically speaking,</p> <p>13 there -- the only data that -- that is available</p> <p>14 for review is -- is what is contained in some of</p> <p>15 the meta-analysis and epidemiology studies</p> <p>16 showing a significant increased risk to ovarian</p> <p>17 cancer based on exposure to talc. And it</p> <p>18 would -- it would only be -- I think it would be</p> <p>19 inappropriate at this time to try to infer what</p> <p>20 percentage of time that would be indicative of</p> <p>21 for exposure.</p> <p>22 Q Have the plaintiffs' lawyers shared</p> <p>23 with you expert reports from their expert</p> <p>24 pathologists who have looked at ovarian tissue of</p>
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<p>1 Objection.</p> <p>2 A I guess my -- I have some -- I guess I</p> <p>3 have some concerns with some of the methodology</p> <p>4 as it relates to the detection of the...</p> <p>5 MS. BROWN:</p> <p>6 Q Do you think it's possible, Doctor, for</p> <p>7 talc to enter the body and -- and be completely</p> <p>8 inert and not cause any reaction?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A So my -- the -- the mechanism I've</p> <p>12 proposed is -- is based -- you know, based on the</p> <p>13 literature, is that talc causes an inflammatory</p> <p>14 response and that inflammatory response is</p> <p>15 supportive of progression to ovarian cancer.</p> <p>16 MS. BROWN:</p> <p>17 Q Does that happen 100 percent of the</p> <p>18 time?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form. In terms of</p> <p>21 inflammatory response or in terms of cancer?</p> <p>22 MS. BROWN:</p> <p>23 Q If you don't understand the question,</p> <p>24 you'll let me know.</p>	<p>1 plaintiffs in this litigation, purported to find</p> <p>2 talc with no foreign body reaction?</p> <p>3 MS. O'DELL:</p> <p>4 Objection. There have been no</p> <p>5 case-specific pathology reports disclosed in the</p> <p>6 litigation we're here about today. And if</p> <p>7 there's something else you're talking about, you</p> <p>8 should be specific.</p> <p>9 A The -- I don't recall a pathology</p> <p>10 report. I've seen expert reports from</p> <p>11 epidemiologists, OB-GYN and -- and some -- and</p> <p>12 other scientists. But I don't recall a specific</p> <p>13 pathology report.</p> <p>14 MS. BROWN:</p> <p>15 Q If the biologically plausible mechanism</p> <p>16 that you posit in your report is true, would you</p> <p>17 expect that the pathology slides of women with</p> <p>18 ovarian cancer who have used talc would evidence</p> <p>19 talcum powder with a foreign body reaction?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Incomplete</p> <p>22 hypothetical.</p> <p>23 A That, I would have to ask how you're</p> <p>24 defining a foreign body reaction.</p>

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<p style="text-align: right;">Page 258</p> <p>1 MS. BROWN: 2 Q Well, would you expect to see some 3 evidence of inflammation in the ovarian tissue of 4 women who used talcum powder products? 5 MS. O'DELL: 6 Object to the form. Incomplete 7 hypothetical. 8 A Overall, speaking to, as we were 9 discussing earlier, the potential for that 10 inflammatory response remains. But given the 11 heterogeneity in individuals, their overall 12 health, their natural variation in the levels of 13 activities of antioxidants, et cetera, I -- I 14 would state that I would expect a variety of 15 magnitude of response to a foreign body like talc 16 among the individuals exposed to it. 17 MS. BROWN: 18 Q You'd expect to see something; right? 19 MS. O'DELL: 20 Object to the form. 21 A No, not necessarily, because it -- it 22 very much depends on the timing that's -- that is 23 observed, how -- what methodology is used to 24 detect the presence of talc or detect the</p>	<p style="text-align: right;">Page 260</p> <p>1 mentioned some of the other subtypes and the 2 common gene mutations that go along with them and 3 as, again, supportive of the same mechanism. And 4 I think, if anything, the -- the current data 5 would suggest a -- a higher prevalence of a 6 particular subtype of cancer but certainly not 7 the -- the mechanism doesn't -- is not exclusive 8 to any one type. 9 Q In your view, all types of epithelial 10 ovarian cancer can be caused by inflammation? 11 A No. That's -- that's not my statement. 12 I would say all types of ovarian cancer are 13 supported by an inflammatory response but that, 14 as from a causative perspective, that's not what 15 the mechanism is provided as an opinion as to 16 cause. It's more that the -- an inflammatory 17 response plays a role in disease initiation 18 and/or progression. 19 Q In your view, Dr. Levy, it is 20 biologically plausible for inflammation to cause 21 all types of epithelial ovarian cancer; true? 22 A Again, I'm not -- I've not been 23 speaking to inflammation as a causative -- as a 24 cause of ovarian cancer. It is a factor in --</p>
<p style="text-align: right;">Page 259</p> <p>1 presence of the inflammatory response, if it's, 2 you know, done histopathologically, if it is 3 based on a reactive oxygen species assay. 4 So given the -- speaking in general 5 terms, I think it's just inappropriate to make a 6 conclusion as to that, yes, you would always 7 expect to see something. 8 I would -- again, to restate what was 9 stated earlier, any -- any exposure has the 10 potential to cause that inflammatory response, 11 and then the time, scale, and magnitude of that 12 response is going to vary by person. Therefore, 13 I would expect there would be a variability in 14 individuals exposed to talc. 15 MS. BROWN: 16 Q Uh-huh. Is your opinion related to all 17 the different histologic types of epithelial 18 ovarian cancer? 19 A My -- my opinion is not exclusive to 20 any -- any one type. Certainly, the epithelial 21 serous being the more common and most virulent 22 type of cancers I think represents the most 23 common. 24 From a mechanistic perspective, I</p>	<p style="text-align: right;">Page 261</p> <p>1 in -- in disease progression. 2 Q So when you conclude, as you do in your 3 report, that talcum powder products cause chronic 4 inflammation, you do not conclude that that 5 chronic inflammation causes ovarian cancer? 6 MS. O'DELL: 7 Object to the form. 8 A I wasn't asked to provide a causation. 9 MS. BROWN: 10 Q Your opinion here is limited to the 11 potential for talcum powder products to produce 12 inflammation; correct? 13 MS. O'DELL: 14 Object to the form. 15 A No. My -- so my opinion is a -- is a 16 supported plausible biological mechanism by which 17 the exposure to talc can lead to ovarian cancer. 18 And, in my opinion, as supported in the -- in the 19 report, that is through an inflammatory response. 20 MS. BROWN: 21 Q I must be missing you, Doctor. So are 22 you of the opinion that inflammation can cause 23 ovarian cancer? 24 A I'm of the opinion that inflammation is</p>

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<p style="text-align: right;">Page 262</p> <p>1 a component of ovarian cancer.</p> <p>2 Q Well, I'm not sure what you mean by</p> <p>3 that. Can inflammation cause ovarian cancer?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form. Asked and</p> <p>6 answered.</p> <p>7 A I'm asked -- I suppose -- again, the</p> <p>8 opinion here is of a mechanistic opinion, not a</p> <p>9 causation. I would defer to some of the</p> <p>10 epidemiology experts to have opinions on</p> <p>11 causation.</p> <p>12 MS. BROWN:</p> <p>13 Q You don't have an opinion on whether or</p> <p>14 not inflammation can cause ovarian cancer?</p> <p>15 MS. O'DELL:</p> <p>16 Different question.</p> <p>17 A Correct. That's a --</p> <p>18 As we've been discussing, my opinions</p> <p>19 are that inflammation is a component of ovarian</p> <p>20 cancer and can be attributed to aspects, not</p> <p>21 exclusively, but contributing to aspects of its</p> <p>22 initiation and aspects of its progression. But I</p> <p>23 did not say that ovarian cancer is caused by</p> <p>24 inflammation.</p>	<p style="text-align: right;">Page 264</p> <p>1 Well, first, we're -- I want to be</p> <p>2 cautious with our use of the word "cause"</p> <p>3 and -- because that's, as we've been discussing,</p> <p>4 this is a -- it is -- it is not controversial</p> <p>5 that ovarian cancer -- inflammation plays a role</p> <p>6 in ovarian cancer and -- and, again, my opinion</p> <p>7 is not towards causation.</p> <p>8 MS. BROWN:</p> <p>9 Q Well, I mean, tumors themselves elicit</p> <p>10 inflammatory responses; right?</p> <p>11 A What -- so what -- specifically, what</p> <p>12 are you referring to?</p> <p>13 Q Well, you talk about tumor-activated</p> <p>14 macrophages in your report; right?</p> <p>15 A Yes.</p> <p>16 Q There is an inflammatory response</p> <p>17 that's produced by the tumor itself; correct?</p> <p>18 A Yes. There are -- there -- there --</p> <p>19 there are absolutely cancer progression markers</p> <p>20 that are associated with continued inflammation.</p> <p>21 Q And that has nothing to do necessarily</p> <p>22 with the events that cause the cancer. Right?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>
<p style="text-align: right;">Page 263</p> <p>1 MS. BROWN:</p> <p>2 Q And what scientific support do you have</p> <p>3 for your opinion that inflammation is a component</p> <p>4 of ovarian cancer and can be attributed to</p> <p>5 aspects of ovarian cancer, including its</p> <p>6 initiation?</p> <p>7 A So, again, the synthesis of the -- of</p> <p>8 the papers we've been discussing, including Saed</p> <p>9 and others, showing the reactive oxygen species</p> <p>10 produced from talc. And, then, as far as</p> <p>11 inflammation and its role in cancer, there</p> <p>12 are -- and it's a fundamentally accepted aspect</p> <p>13 of cancer biology that's been around for -- for</p> <p>14 quite some time. And we mentioned earlier that</p> <p>15 there's a variety of review articles, including</p> <p>16 the ones we were comparing sentences to earlier</p> <p>17 today, that describe that in great detail.</p> <p>18 Q It's not generally accepted, though,</p> <p>19 that ovarian cancer is caused by inflammation.</p> <p>20 Fair?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A I think there's a number of studies</p> <p>24 that --</p>	<p style="text-align: right;">Page 265</p> <p>1 A Well, so the -- we -- we would be going</p> <p>2 down a slightly different road. And if</p> <p>3 we're -- so cancer as a complex disorder, you</p> <p>4 know, begins with an initiating event. But there</p> <p>5 is -- there is absolutely tumor evolution from</p> <p>6 that initial event through the progression of the</p> <p>7 disease.</p> <p>8 So to state that the -- in the initial</p> <p>9 inflammatory response to the tumor is -- is not</p> <p>10 causative to the continuation of the disease I</p> <p>11 think would be incorrect.</p> <p>12 MS. BROWN:</p> <p>13 Q The Penninkilampi authors -- to</p> <p>14 conclude our discussion here -- concluded that</p> <p>15 the paragraph you were looking at with the</p> <p>16 sentence "The potential mechanism by which</p> <p>17 genital talc is associated with an increased risk</p> <p>18 of ovarian cancer, hence, remains unclear," do</p> <p>19 you see that?</p> <p>20 A Yes.</p> <p>21 Q And this meta-analysis was published in</p> <p>22 January of 2018; correct?</p> <p>23 A Correct.</p> <p>24 Q And it is, in fact, cited in the</p>

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<p style="text-align: right;">Page 266</p> <p>1 majority of the plaintiff expert reports in this 2 litigation. Did you see that? 3 MS. O'DELL: 4 Object to the form. If you know that. 5 Don't speculate. 6 MS. BROWN: 7 Q That's why I asked "Did you see that?" 8 A So I didn't specifically look at if 9 this was referenced. I -- I certainly referenced 10 it. But I would also point out another important 11 part of the -- of this same reference, a -- about 12 halfway down the following paragraph, beginning 13 with "If chronic inflammation due to ascending 14 foreign bodies is indeed the mechanism by which 15 talc use is associated with ovarian cancer risks, 16 then these results fit the picture." 17 So I think the authors were both 18 describing some things that remain unclear but 19 also offering some comments that are supportive 20 of our earlier discussions today on this 21 mechanism. 22 Q And your opinion here today, Doctor, is 23 limited to the potential mechanism; right? 24 MS. O'DELL:</p>	<p style="text-align: right;">Page 268</p> <p>1 available data that there is a biologically 2 plausible mechanism surrounding and, indeed, in 3 the previous paragraph at the end of it where 4 they discuss use of -- or expression of 5 cyclooxygenase 1 and 2 as well as the action of 6 NSAIDs, again, supportive of -- somewhat 7 supportive of the inflammatory model. But... 8 MS. BROWN: 9 Q Well, as it relates to the NSAIDs, 10 Doctor, they point to the fact that the NSAID 11 data is inconsistent, at best, as evidence 12 supportive of their conclusions that the 13 mechanism is unclear; right? 14 A No. They point to it as -- they 15 actually try to clarify that the -- the seemingly 16 contradictory data regarding the NSAID use can be 17 explained by the relatively low expression of 18 cyclooxygenase 1 and cyclooxygenase 2, which are 19 the targets of most common NSAIDs. 20 Q What they say is that the use of 21 nonsteroidal anti-inflammatory drugs, NSAIDs, is 22 not inversely associated with the incidence of 23 ovarian cancer as may be expected if the etiology 24 was related to chronic inflammation. Right?</p>
<p style="text-align: right;">Page 267</p> <p>1 Object to the form. 2 A So my -- my opinion is -- is -- is 3 regarding a biologically plausible mechanism. 4 But, then -- and, in doing so, have reviewed some 5 of these studies that we're discussing now. 6 MS. BROWN: 7 Q Good. 8 And, as it relates to that potential 9 mechanism, these Penninkilampi authors conclude 10 that the potential mechanism remains unclear. 11 Right? 12 MS. O'DELL: 13 Objection to form. 14 A They -- the article makes a statement, 15 "The potential mechanism by which genital talc is 16 associated with an increased risk of ovarian 17 cancer, hence, remains unclear." 18 However, as we've been discussing, they 19 go on to state, "If chronic inflammation due to 20 ascending foreign body is indeed the mechanism," 21 then there -- the results in this paper 22 are -- fit that model. 23 So I think they're making reason- -- 24 making reasonable statements based on the</p>	<p style="text-align: right;">Page 269</p> <p>1 MS. O'DELL: 2 Objection to form. 3 A Yes, that statement is made. But, 4 importantly, it is incomplete without the next 5 sentence, again, explaining that -- that 6 apparent -- that apparent question. 7 So if the -- if NSAIDs are not 8 effective in ovarian cancer and the -- and, in 9 turn -- and if the observation is also made that 10 ovarian cancer cells don't express cyclooxygenase 11 1 and 2, then they would not -- they would be 12 nonresponsive to NSAIDs. 13 Q You state on page 12 of your report, 14 Doctor, in the last paragraph, the second-to-last 15 sentence that begins "moreover," that the effect 16 of nonsteroidal anti-inflammatory drugs, NSAIDs, 17 to reduce the risk of ovarian cancer provides 18 additional support for what you're discussing 19 here, which is that chronic inflammation plays a 20 key role in the development of ovarian cancer. 21 Right? 22 A Correct. 23 Q And that is, in fact, the opposite of 24 what the authors in Penninkilampi report as</p>

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<p>1 relates to NSAIDs; right?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A Not -- not necessarily. So there's --</p> <p>5 getting back to the -- the specific cells under</p> <p>6 question and the inflammatory response being</p> <p>7 examined. And, so, if we are lowering overall</p> <p>8 chronic inflammation through the use of an NSAID</p> <p>9 is -- is one question. A separate question is is</p> <p>10 a -- is a ovarian cancer cell responsive to</p> <p>11 NSAIDs. So they're two separate biological</p> <p>12 phenomenon.</p> <p>13 And, in one case, if those cells are</p> <p>14 not expressing the cyclooxygenase 1 and 2,</p> <p>15 they'll be nonresponsive.</p> <p>16 I would speculate that NSAID use in the</p> <p>17 rest of the body would still result in the</p> <p>18 expected effect due to, you know, the -- due to</p> <p>19 the inhibition of cyclooxygenase 1 and 2.</p> <p>20 So I don't think they're necessarily in</p> <p>21 conflict with each other.</p> <p>22 (DEPOSITION EXHIBIT NUMBER 20</p> <p>23 WAS MARKED FOR IDENTIFICATION.)</p> <p>24 MS. BROWN:</p>	<p>1 statement.</p> <p>2 And then there was, I think,</p> <p>3 importantly, the Lin 2011 paper is also relevant.</p> <p>4 Q Well, as it relates to the Merritt</p> <p>5 paper, this cite is wrong; right?</p> <p>6 A I need a moment to --</p> <p>7 Q Let's look at what Merritt actually</p> <p>8 found about pelvic inflammatory disease.</p> <p>9 If you look --</p> <p>10 MS. O'DELL:</p> <p>11 If you need a moment --</p> <p>12 Excuse me. I'm sorry. I didn't mean</p> <p>13 to interrupt you.</p> <p>14 If you need a moment to refresh</p> <p>15 yourself, Dr. Levy, please do.</p> <p>16 MS. BROWN:</p> <p>17 Q Sure. And if you -- when you're ready,</p> <p>18 Doctor, I'll direct you to the second column on</p> <p>19 page 174, and I want to talk about the last</p> <p>20 paragraph there that begins "if inflammation."</p> <p>21 A Page?</p> <p>22 Q And I'll read it into the record while</p> <p>23 you orient yourself. It's page 174, right-hand</p> <p>24 column. Final paragraph states, "If inflammation</p>
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<p>1 Q Handing you what we've marked as</p> <p>2 Defense Exhibit 20 to your deposition, this is a</p> <p>3 paper by Merritt entitled "Talcum Powder Chronic</p> <p>4 Pelvic Inflammation and NSAIDs in Relation to the</p> <p>5 Risk of Epithelial Ovarian Cancer."</p> <p>6 Do you see that?</p> <p>7 A I do.</p> <p>8 Q And, in fact, on page 12 of your</p> <p>9 report, you cite this Merritt article. Correct?</p> <p>10 A Yes. Uh-huh.</p> <p>11 Q And you cite it for the proposition</p> <p>12 that studies have found a relationship between</p> <p>13 pelvic inflammatory disease and ovarian cancer</p> <p>14 risk. Correct?</p> <p>15 A Correct.</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 MS. BROWN:</p> <p>19 Q And you point to Merritt when you</p> <p>20 determine here as a finding of a relationship</p> <p>21 between pelvic inflammatory disease and ovarian</p> <p>22 cancer in support of your opinion that</p> <p>23 inflammation can cause ovarian cancer. True?</p> <p>24 A I'd have to double-check that</p>	<p>1 plays a role in the etiology of ovarian cancer,</p> <p>2 then it would be expected that PID would be</p> <p>3 associated with increased risks of ovarian</p> <p>4 cancer. PID is not associated with elevated risk</p> <p>5 of ovarian tumors in our data, confirming several</p> <p>6 previous reports of no association with PID in</p> <p>7 studies of all subtypes of ovarian cancer."</p> <p>8 Did I read that correctly?</p> <p>9 A You did.</p> <p>10 Q All right. So you cited this study for</p> <p>11 the proposition that studies have found a</p> <p>12 relationship between PID and ovarian cancer risk.</p> <p>13 Right?</p> <p>14 A No. I said -- I cited -- I said</p> <p>15 studies have found a relationship, yes, between</p> <p>16 PID and ovarian cancer risk.</p> <p>17 Q And, in fact, this study did not find a</p> <p>18 relationship between PID and ovarian cancer risk.</p> <p>19 Right?</p> <p>20 A I think this study found a -- I'm just</p> <p>21 looking at the...</p> <p>22 So -- I'm sorry. Would you ask your</p> <p>23 question again? This -- this study did not</p> <p>24 find your --</p>

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<p style="text-align: right;">Page 274</p> <p>1 Yes, I --</p> <p>2 Q Sure. I just -- you cited this study</p> <p>3 for the proposition that it showed there was a</p> <p>4 relationship between pelvic inflammatory disease</p> <p>5 and ovarian cancer risk, but, in fact, the study</p> <p>6 showed the opposite. Correct?</p> <p>7 A Well, to be clear on the wording,</p> <p>8 stated that the studies have found a</p> <p>9 relationship. I didn't indicate whether it was</p> <p>10 positive or negative.</p> <p>11 But I think, importantly, the study</p> <p>12 also has an important paragraph that is probably</p> <p>13 more related to its inclusion, which is on the</p> <p>14 same page we were just on, 174, second full</p> <p>15 paragraph in the discussion.</p> <p>16 Q One of the things on this page,</p> <p>17 Doctor --</p> <p>18 MS. O'DELL:</p> <p>19 Are you finished, Doctor?</p> <p>20 A I think important to at least finish</p> <p>21 that thought.</p> <p>22 That paragraph reads, "Focusing on talc</p> <p>23 use, we found that any use of perineal talc was</p> <p>24 associated with a small but significantly</p>	<p style="text-align: right;">Page 276</p> <p>1 quote, "We conclude that, on balance, chronic</p> <p>2 inflammation does not play a major role in the</p> <p>3 development of ovarian cancer."</p> <p>4 Q Do you see that, Doctor?</p> <p>5 A I see that.</p> <p>6 Q And what this study did was it</p> <p>7 endeavored to look into factors potentially</p> <p>8 associated with ovarian inflammation to see if it</p> <p>9 could support the theory that chronic</p> <p>10 inflammation plays a role in ovarian cancer;</p> <p>11 right?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A I would need to -- this one limitation</p> <p>15 of this particular paper is that it is connecting</p> <p>16 inflammation as evidenced by pelvic inflammatory</p> <p>17 disease and assuming that that source and type of</p> <p>18 inflammation would be -- the fact that there's</p> <p>19 not a direct association between -- or an</p> <p>20 increased risk of ovarian cancer in the presence</p> <p>21 of pelvic inflammatory disease; therefore,</p> <p>22 inflammation must not play a role in ovarian</p> <p>23 cancer. So that is their conclusions.</p> <p>24 MS. BROWN:</p>
<p style="text-align: right;">Page 275</p> <p>1 increased risk of ovarian cancer overall and</p> <p>2 specifically amongst the invasive and LNP serous</p> <p>3 tumors, although no clear dose response with</p> <p>4 increase in duration of use was identified. This</p> <p>5 finding is consistent with results of previous</p> <p>6 studies."</p> <p>7 So in the case of the report and the</p> <p>8 biologically plausible mechanism that's been</p> <p>9 supported by these studies, these studies</p> <p>10 differentiating the process of pelvic</p> <p>11 inflammatory disease doesn't ex- -- doesn't</p> <p>12 exclude or refute the inflammatory role or the</p> <p>13 role inflammation may play in ovarian cancer.</p> <p>14 Q What this study concludes is that, on</p> <p>15 balance, chronic inflammation does not play a</p> <p>16 major role in the development of ovarian cancer.</p> <p>17 Do you recall reviewing this in connection with</p> <p>18 your opinions in this case?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form. Misstates the</p> <p>21 exhibit.</p> <p>22 MS. BROWN:</p> <p>23 Counsel, I'll direct you to the last</p> <p>24 paragraph of the abstract on page 1 which reads,</p>	<p style="text-align: right;">Page 277</p> <p>1 Q Well, they looked at a bunch of</p> <p>2 different inflammatory conditions, didn't they?</p> <p>3 That was the focus of the study. The authors</p> <p>4 endeavored to look at a number of different</p> <p>5 pro-inflammatory factors and see if they</p> <p>6 influenced ovarian cancer. Do you recall</p> <p>7 reviewing that?</p> <p>8 A I do. I think -- but, more</p> <p>9 importantly, when we look at the -- their</p> <p>10 specific statements that are surrounding the</p> <p>11 mechanism we're discussing today, which has to do</p> <p>12 with talc exposure and perineal talc use, I think</p> <p>13 their -- their statements in that sense, which</p> <p>14 have already been read, quite stand on their own.</p> <p>15 So what this may indicate is a variety</p> <p>16 of types of inflammation do -- as present in</p> <p>17 other diseases, those individually do not or may</p> <p>18 not have a specific role in the progression of</p> <p>19 ovarian cancer.</p> <p>20 But it does not -- again, it does not</p> <p>21 mean that ovarian inflammation at the site of</p> <p>22 talc exposure in the ovary can't have a role in</p> <p>23 the progression of disease where -- again, as we</p> <p>24 were discussing earlier, with inflammation, we're</p>

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<p style="text-align: right;">Page 278</p> <p>1 now connecting independent biological processes.</p> <p>2 And I think you're -- I want to be sure</p> <p>3 we're clear and not drawing the use of the word</p> <p>4 "chronic inflammation" as meaning any</p> <p>5 inflammation and, therefore, if it's not</p> <p>6 associated with ovarian cancer, that inflammation</p> <p>7 can't have a role.</p> <p>8 What we're speaking about in terms of</p> <p>9 this mechanism is inflammation caused by the</p> <p>10 perineal use of talcum powder in the ovary and</p> <p>11 the -- and the -- to explain that increased risk</p> <p>12 of ovarian cancer, what is a plausible mechanism.</p> <p>13 Q The authors write, on page 74 -- 174,</p> <p>14 Doctor, second column, paragraph that begins with</p> <p>15 "It has been hypothesized," "It has been</p> <p>16 hypothesized that talc is linked to ovarian</p> <p>17 cancer development through inflammation," comma,</p> <p>18 "however evidence linking an inflammatory</p> <p>19 response with talc contamination of the ovaries</p> <p>20 is lacking."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q And you disagree with that statement?</p> <p>24 A I would -- I would suggest that a</p>	<p style="text-align: right;">Page 280</p> <p>1 couple times, and that's a 1.17 relative risk</p> <p>2 that you're referring to. Is that right?</p> <p>3 A Where is that?</p> <p>4 Q I'm looking at -- in the abstract.</p> <p>5 A Yes.</p> <p>6 Q Right. And the confidence interval is</p> <p>7 1.01 to 1.36. Right?</p> <p>8 A Correct.</p> <p>9 MS. O'DELL:</p> <p>10 As to what finding?</p> <p>11 MS. BROWN:</p> <p>12 The one we're discussing.</p> <p>13 Q And, Doctor, you know that one -- a</p> <p>14 confidence interval that begins with one is not</p> <p>15 statistically significant?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 MS. BROWN:</p> <p>19 Q Did you know that?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A Well, I would say the authors have</p> <p>23 stated in that abstract that it is statistically</p> <p>24 significant.</p>
<p style="text-align: right;">Page 279</p> <p>1 number of studies in the literature since the</p> <p>2 publication of this paper would -- would suggest</p> <p>3 that these conclusions may have been premature.</p> <p>4 Q Do you think that, at the time this</p> <p>5 paper was published in 2008, that Merritt was</p> <p>6 accurately representing the data as it related to</p> <p>7 whether chronic inflammation could play a role in</p> <p>8 the development of ovarian cancer?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A I would say that Merritt has an</p> <p>12 unresolved -- has a number of unresolved</p> <p>13 conclusions or partial conclusions in their</p> <p>14 paper, again, including the paragraph we've</p> <p>15 discussed where they comment on the talc use with</p> <p>16 an increased risk of ovarian cancer.</p> <p>17 MS. BROWN:</p> <p>18 Q Did you see the confidence interval on</p> <p>19 that finding, Doctor?</p> <p>20 A I'd have to -- in --</p> <p>21 Is this in this paper or in the number</p> <p>22 of the --</p> <p>23 Q You reference the finding of an</p> <p>24 association between talc use and ovarian cancer a</p>	<p style="text-align: right;">Page 281</p> <p>1 MS. BROWN:</p> <p>2 Q Sure, because it's 1.01. My question</p> <p>3 to you was do you know that a confidence interval</p> <p>4 that begins with one is not statistically</p> <p>5 significant?</p> <p>6 This finding, Doctor, is barely</p> <p>7 statistically significant, isn't it?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A Again -- again, it's a -- whether it's</p> <p>11 barely or whether it's tremendously statistically</p> <p>12 significant, it -- it's still a finding that I</p> <p>13 would say is in support of -- has been supported</p> <p>14 by other studies with similar relative risk</p> <p>15 numbers in the -- in the 1.2 range and above, as</p> <p>16 indicated.</p> <p>17 MS. BROWN:</p> <p>18 Q Finally, Doctor, at the very -- the</p> <p>19 very last sentence of this Merritt study we're</p> <p>20 discussing, on page 175, concludes, "However,</p> <p>21 experimental evidence that perineal talc use</p> <p>22 elicits an inflammatory response in the ovaries</p> <p>23 is lacking, and overall we conclude that chronic</p> <p>24 inflammation does not play a major role in the</p>

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<p style="text-align: right;">Page 282</p> <p>1 development of ovarian cancer." 2 And my question for you is what 3 methodology did you employ to consider the 4 findings of the Merritt paper in coming to your 5 opinions contained in your report? 6 MS. O'DELL: 7 Object to the form. 8 A Again, as we've discussed earlier here 9 today, the -- there's been no singular paper that 10 had a specific role in -- in developing the 11 biologically plausible mechanism contained in the 12 report. And, so, this -- this paper, among many 13 others, was -- was used. 14 MS. BROWN: 15 Q Right. But the findings of this paper 16 is that talcum powder doesn't produce an 17 inflammatory response that leads to cancer. 18 Right? 19 A The -- the findings of this paper was 20 that there's not an association of pelvic 21 inflammatory disease and risk of ovar- -- of 22 epithelial ovarian cancer. 23 Q They conclude that chronic inflammation 24 doesn't play a role in the development of ovarian</p>	<p style="text-align: right;">Page 284</p> <p>1 Again, the observations in this paper 2 are regarding chronic inflammation and its -- and 3 its major role in the development of ovarian 4 cancer; and, again, in this -- in the specific 5 individuals that they've looked at, it's in 6 regards to pelvic inflammatory disease. 7 And, so, as far as weighting that 8 paper, it would be similar to other papers and 9 other observations in the sense that it was -- 10 that the mechanism that is supported by a wide 11 variety of work considers a history of -- history 12 of work in the talc, inflammation, and ovarian 13 cancer fields both in basic research and 14 epidemiology to come up -- to come to the 15 conclusions and mechanisms that are proposed. 16 I don't -- I can't give you a specific 17 weighting algorithm that was used on any -- any 18 given paper. 19 MS. BROWN: 20 Q Did you consider Merritt's finding that 21 evidence linking an inflammatory response with 22 talc of the ovaries is lacking? 23 A I certainly considered their -- I 24 considered their statements in the -- in the</p>
<p style="text-align: right;">Page 283</p> <p>1 cancer; right? 2 A I think they've -- they've extended 3 that observation regarding pelvic inflammatory 4 disease to that conclusion. 5 But I think the studies that have come 6 after this and other -- certainly other areas of 7 review would suggest that those specific -- the 8 wording of those specific statements may not be 9 the most appropriate representation of the -- of 10 the observations made in the -- in the Merritt 11 paper. 12 Q So did you weight the Merritt paper 13 less than some other papers that came after it? 14 Or how did you -- 15 What I'm trying to understand is your 16 methodology for considering this paper, which 17 seems to squarely conclude talc doesn't cause 18 inflammation. 19 MS. O'DELL: 20 Object to the form. 21 A I'm not -- so I would -- I would 22 disagree that -- this paper does not make those 23 conclusions that talc does not cause 24 inflammation. What they --</p>	<p style="text-align: right;">Page 285</p> <p>1 paper. And I would question the dichotomy of 2 the -- of some of their statements regarding talc 3 risk to cancer. 4 And the first question that would come 5 to mind for this particular study is how they 6 assessed talc-related inflammation in -- 7 specifically in the ovary. I don't recall seeing 8 how they made that assessment. 9 It, instead, seemed to me that their 10 assessments were based on chronic inflammation as 11 it related to other biological conditions and 12 then extrapolating that to rate of ovarian 13 cancer. 14 Q How do you think one should measure 15 talc-related inflammation in the ovary? 16 MS. O'DELL: 17 Object to the form. 18 A Again, I wasn't asked to -- to provide 19 that opinion. But I would reference the more 20 recent Saed paper which -- and other molecular -- 21 and other molecular studies and certainly defer 22 to Dr. Saed as an expert witness to discuss 23 appropriate measurements for talc-related 24 inflammation in the -- in the ovary or ovarian</p>

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<p style="text-align: right;">Page 286</p> <p>1 cells.</p> <p>2 MS. BROWN:</p> <p>3 Q Have you spoken with Dr. Saed?</p> <p>4 A I have not.</p> <p>5 Q Have you requested any information from</p> <p>6 Dr. Saed?</p> <p>7 A No, I have not.</p> <p>8 Q Have you -- would you hold to the same</p> <p>9 opinion if you did not consider the work of</p> <p>10 Dr. Saed?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form. Vague.</p> <p>13 A I -- the work of Dr. Saed is -- is a</p> <p>14 consideration among the wide variety of other</p> <p>15 literature contained in here. And Dr. Saed's</p> <p>16 work for in vitro analysis and the quantitation</p> <p>17 of specific reactive oxygen species is -- is a</p> <p>18 factor in and it is in support of the mechanism</p> <p>19 that I've proposed, which is that that mechanism</p> <p>20 does not rely on that study or any singular study</p> <p>21 for it to be valid.</p> <p>22 MS. BROWN:</p> <p>23 Q The mechanism you proposed, Doctor, is</p> <p>24 not yet generally accepted in the scientific</p>	<p style="text-align: right;">Page 288</p> <p>1 biologically plausible mechanism that was also</p> <p>2 peer-reviewed, and I would rely on or point you</p> <p>3 to a number of other expert reports, particularly</p> <p>4 in the epidemiology space from this case, where</p> <p>5 you'll find a great many parallels to -- to this</p> <p>6 case.</p> <p>7 So I, instead, would state</p> <p>8 independently myself and other respected</p> <p>9 scientists have essentially developed the same</p> <p>10 opinions regarding mechanism in this -- in this</p> <p>11 particular space.</p> <p>12 MS. BROWN:</p> <p>13 Q Is there another plaintiffs' expert</p> <p>14 that you're aware of who holds the same opinion</p> <p>15 as you do on biological plausibility?</p> <p>16 A Yes.</p> <p>17 Q Who's that?</p> <p>18 A Patricia Moorman, who is an</p> <p>19 epidemiologist whose report I had the opportunity</p> <p>20 to read yesterday.</p> <p>21 Q Is there -- and -- and even though</p> <p>22 she's an epidemiologist, Dr. Moorman has a view</p> <p>23 on biological plausibility? Is that right?</p> <p>24 MS. O'DELL:</p>
<p style="text-align: right;">Page 287</p> <p>1 community. Would you agree?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A I wouldn't have a basis for that</p> <p>5 opinion. As -- as we talked about earlier, I</p> <p>6 haven't shared this mechanism to ask for that</p> <p>7 opinion.</p> <p>8 MS. BROWN:</p> <p>9 Q You haven't published the proposed</p> <p>10 mechanism that is the subject of your report. Is</p> <p>11 that right?</p> <p>12 A That's right.</p> <p>13 Q You haven't discussed the proposed</p> <p>14 mechanism that is the subject of your report with</p> <p>15 any of your colleagues at HudsonAlpha; correct?</p> <p>16 A That's correct.</p> <p>17 Q So whether or not the proposed</p> <p>18 mechanism that is the subject of your report</p> <p>19 would be accepted by your peers in the scientific</p> <p>20 community, that's not something you have yet</p> <p>21 evaluated; correct?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A My -- I wasn't requested to provide a</p>	<p style="text-align: right;">Page 289</p> <p>1 Object to the form.</p> <p>2 A She has a view on --</p> <p>3 In her report was a -- a view on</p> <p>4 mechanism -- on mechanism, which included the</p> <p>5 discussion of inflammatory response and its role</p> <p>6 in ovarian cancer, which parallels this report.</p> <p>7 MS. BROWN:</p> <p>8 Q Do you consider your proposed mechanism</p> <p>9 that is the subject of your report to be a novel</p> <p>10 concept in the scientific world?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A Which part?</p> <p>14 MS. BROWN:</p> <p>15 Q Any part.</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A Again, I -- my -- the -- what was</p> <p>19 requested of me was not to develop a novel</p> <p>20 concept or even to describe an untested</p> <p>21 hypothesis. What was requested of me was to</p> <p>22 review the available literature and provide a</p> <p>23 biologically plausible mechanism for talc</p> <p>24 exposure to ovarian cancer. And, so, that's</p>

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<p style="text-align: right;">Page 290</p> <p>1 what -- that's what my report provides. 2 MS. BROWN: 3 Q Do you think there could be other 4 biologically plausible mechanisms by which talcum 5 powder would be associated with ovarian cancer? 6 A I haven't been asked to -- to make a 7 review related to other biological mechanisms. I 8 was asked to develop a biologically plausible 9 mechanism. And upon review of the totality of 10 the literature, this mechanism that -- that I've 11 presented and provided in the report is, in my 12 opinion, the correct mechanism. 13 Q Did you have complete autonomy in your 14 task to develop a biologically plausible 15 mechanism? 16 A Yes. 17 Q Were there any limitations on how you 18 should go about developing this biologically 19 plausible limita- -- mechanism? 20 MS. O'DELL: 21 Object to the form of the question to 22 the degree that the question seeks -- 23 MS. BROWN: 24 Form.</p>	<p style="text-align: right;">Page 292</p> <p>1 for you here, Doctor, is, were -- was there any 2 limitation placed on you that you relied on in 3 trying to develop your biologically plausible 4 mechanism? 5 MS. O'DELL: 6 What's allowed -- you're well aware of 7 this, counsel, I know -- that what's discoverable 8 is are there materials considered -- you can ask 9 him that -- was there assumptions that he was 10 asked to make -- that's discoverable -- and the 11 compensation. Those are the three things. Not 12 conversations between counsel and Dr. Levy. 13 So -- 14 MS. BROWN: 15 Counsel, you can instruct or we'll get 16 the judge. We do not have time for your 17 speeches. We're trying to finish up and let 18 other people -- other people ask questions. 19 MS. O'DELL: 20 That's straight from the rules. You're 21 well aware of that. 22 MS. BROWN: 23 So here's the question. If you want to 24 instruct, we'll take a break and get the judge.</p>
<p style="text-align: right;">Page 291</p> <p>1 MS. O'DELL: 2 No, no. If it goes to conversations 3 with counsel, it is not form. It is 4 attorney-client privilege and it's protected. 5 Work product privilege is protected. 6 And, so, Dr. Levy -- 7 MS. BROWN: 8 No. Counsel -- 9 MS. O'DELL: 10 Excuse me. Excuse me. I'm directing 11 my witness based on privilege, and I can do that. 12 To the degree that counsel is trying to 13 seek the substance of discussions you had with 14 counsel, those are protected, and I direct you 15 not to answer. 16 To the degree there's something in your 17 mind to respond that's not that, you may -- you 18 may respond. 19 MS. BROWN: 20 Q And as -- as counsel well knows, 21 because we've had this discussion earlier this 22 week, the federal rules allow discovery of any 23 material you relied on in forming your opinions. 24 And, so, my answer here -- my question</p>	<p style="text-align: right;">Page 293</p> <p>1 Q Did you rely on any instruction from 2 counsel regarding any limitations on how you were 3 to attempt to develop your biologically plausible 4 mechanism? 5 A No. I was -- I was not provided -- 6 there were no -- 7 I'm trying to make sure I answer to be 8 correct. But my very simple and direct answer is 9 the requests for the report were very succinct 10 and were given without limitation. 11 Q Did you try to develop any mechanism 12 that you rejected in connection with your report? 13 MS. O'DELL: 14 Object to the form. Vague. 15 A So I would best answer that by saying I 16 did not develop an initial mechanism and, 17 instead, began a literature review looking at the 18 available literature in talcum powder 19 inflammation in cancer, ovarian cancer, and then 20 in related subjects, and then, through the course 21 of that review, was able to synthesize the 22 opinion that you have, that we've been 23 discussing, in the report. 24 MS. BROWN:</p>

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<p style="text-align: right;">Page 294</p> <p>1 Q Do you consider the biologically</p> <p>2 plausible mechanism that is the subject of your</p> <p>3 report to be a hypothesis?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form. Asked and</p> <p>6 answered.</p> <p>7 A No, no. In fact, it is not. And</p> <p>8 it's -- I think it's very fundamentally different</p> <p>9 than a hypothesis.</p> <p>10 Because, again, to state, the</p> <p>11 activities that were undertaken was a review of</p> <p>12 the literature and then, based on that review, a</p> <p>13 mechanism that was biologically plausible. It is</p> <p>14 not hypothetical.</p> <p>15 MS. BROWN:</p> <p>16 Q Have you tested your biologically</p> <p>17 plausible mechanism?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A Tested in the sense of --</p> <p>21 So I would -- I would answer that as --</p> <p>22 in -- in my opinion, I would suggest that this</p> <p>23 has been tested based on following the completion</p> <p>24 of the report and reading other similarly derived</p>	<p style="text-align: right;">Page 296</p> <p>1 mechanism, you mean other experts in this</p> <p>2 litigation?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form. Misstates his</p> <p>5 testimony.</p> <p>6 A Other -- other material -- the</p> <p>7 materials that I was -- that I was provided.</p> <p>8 MS. BROWN:</p> <p>9 Q And those materials are in the form of</p> <p>10 other expert reports like yours; right?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A They are.</p> <p>14 MS. BROWN:</p> <p>15 Q Are you aware of any nonlitigation</p> <p>16 expert that has arrived at the same biologically</p> <p>17 plausible proposed mechanism as you?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A Well, I think -- yeah, in the sense --</p> <p>21 in the sense of the number of publications we've</p> <p>22 been discussing and some of the more recent both</p> <p>23 reviews and -- and Saed's paper, I suppose, as</p> <p>24 we've been discussing, Dr. Saed has been funded</p>
<p style="text-align: right;">Page 295</p> <p>1 or similarly requested both literature, some of</p> <p>2 the publications that we've been discussing, as</p> <p>3 well as other expert reports that have, as we've</p> <p>4 just discussed, some parallel aspects.</p> <p>5 So, from a formal scientific process,</p> <p>6 that is -- would not, I think, be considered a</p> <p>7 formal test. But from the perspective of this</p> <p>8 biologically plausible mechanism, other</p> <p>9 scientists undertaking similar methodology came</p> <p>10 up with similar results.</p> <p>11 And, so, therefore, I would say that</p> <p>12 this report is -- continues to be supported by</p> <p>13 independent reviews and content.</p> <p>14 MS. BROWN:</p> <p>15 Q The other scientists that you just</p> <p>16 referenced are also paid experts for the</p> <p>17 plaintiffs; is that right?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I don't have knowledge of that</p> <p>21 specifically.</p> <p>22 MS. BROWN:</p> <p>23 Q Well, when you said other experts</p> <p>24 looking at the same thing came up with a similar</p>	<p style="text-align: right;">Page 297</p> <p>1 for some of this work, but I would counter that</p> <p>2 with sponsorship of -- of studies that are</p> <p>3 subsequently peer-reviewed, I think are generally</p> <p>4 held to a scientific standard and rigor, and</p> <p>5 would suggest that his most recent work would</p> <p>6 fall under that and -- and, therefore, I would</p> <p>7 not consider that in the same realm as an expert</p> <p>8 report.</p> <p>9 MS. BROWN:</p> <p>10 Q Are you aware that the plaintiffs'</p> <p>11 lawyers funded Dr. Saed's studies?</p> <p>12 A I am.</p> <p>13 Q How do you know that?</p> <p>14 MS. O'DELL:</p> <p>15 Don't speculate. If you know it,</p> <p>16 testify to it.</p> <p>17 A No. I'm thinking of --</p> <p>18 That was disclosed during the</p> <p>19 discussion of the -- of the paper, and the</p> <p>20 question I asked and actually looked on the paper</p> <p>21 was to --</p> <p>22 And this -- this was getting to my own</p> <p>23 opinion as to the appropriateness and the</p> <p>24 potential scientific rigor of the paper, and that</p>

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<p style="text-align: right;">Page 298</p> <p>1 was whether or not Dr. Saed disclosed that 2 relationship, which is, of course, ethically a 3 requirement for sponsored research. And, indeed, 4 that sponsorship is made in the paper. 5 MS. BROWN: 6 Q Was it important to you -- 7 Did you ask Dr. Saed about the funding 8 for his paper? 9 A I did not. As we -- as we discussed, I 10 haven't spoken with him. 11 Q Were you troubled by the fact that 12 Dr. Saed's disclosure does not reference which 13 side of the litigation he's working for? 14 MS. O'DELL: 15 Object to the form. 16 A Are you asking for my opinion on if it 17 troubled me? 18 MS. BROWN: 19 Q Yeah. 20 A No. 21 Q It sounds like you did a little 22 investigation and you were satisfied with the 23 disclosure. Was that your testimony? 24 MS. O'DELL:</p>	<p style="text-align: right;">Page 300</p> <p>1 Q Why is it important, in your mind, to 2 disclose funding for a study? 3 A Well, it's, you know, ethical premise 4 of -- of most scientific research or really all 5 extramurally funded research that the funding 6 sources are -- are always disclosed. And that's 7 true for publication as well as presentation. 8 And, so, I think most -- most 9 scientists, during presentation, will present a 10 slide that shows their -- their funding support 11 and all of its sources regard- -- whether it's 12 public or private. 13 And then you'll notice in vast majority 14 of publications, if they are grant supported, 15 again, whether that grant is from a public or a 16 private institution, those things are referenced. 17 And, in fact, the U. S. Government has a 18 requirement that grants be referenced in their -- 19 in any publications that were supported by that 20 money. 21 Q Do you have any critiques of either of 22 Saed's papers? 23 A No. Not at this time. 24 Q Do you have any questions or anything</p>
<p style="text-align: right;">Page 299</p> <p>1 Object to the form. He didn't use the 2 word "investigation." 3 A I was satisfied seeing a disclosure 4 made regarding funding, which, again, in the 5 scientific climate I would -- or I would state 6 simply I viewed the support of that study which 7 subsequently goes out to peer review functionally 8 equivalent to pharmaceutical support of a study 9 involving a drug or a condition or a treatment. 10 The reality of the scientific space 11 is -- is -- is funding sponsorship comes from a 12 variety of cases. And in each institution, 13 HudsonAlpha certainly, I'm positive Wayne State 14 has a conflict of interest review board which 15 Dr. Saed has to report to as far as the -- how he 16 manages that potential conflict of interest. And 17 given that he's at a reputable institution that 18 I've actually done a fair amount of review work 19 with over the years, being Wayne State, I'm 20 reasonably -- or I would say I'm quite confident 21 that his conflict of interest has been managed 22 appropriately for the -- for the study that was 23 reviewed. 24 MS. BROWN:</p>	<p style="text-align: right;">Page 301</p> <p>1 that doesn't make sense to you, having reviewed 2 the most recent one or the 2017 one? 3 A No. My focus, particularly on the most 4 recent one, I actually found his molecular 5 studies to be quite comprehensive and -- 6 So there was -- there was no specific 7 concerns that -- that I was able to identify. 8 And, again, the -- in the -- in the version of 9 the paper that -- that I -- that I was given. 10 Q And did you have any opportunity to 11 check to see if you had an earlier version of 12 that paper? 13 A Oh, I -- I'll be sure and do that at 14 the next break. 15 Q Okay. Why don't we go ahead and take a 16 break now. You'll take a look, if you wouldn't 17 mind, to see if you have something other than 18 what we've marked at the deposition. 19 I'm going to renew -- review my notes. 20 I'm close to finishing, and then I'll hand it 21 over to my colleague, Mr. Ferguson, who I think 22 will have some questions for you as well. Okay, 23 Doctor? 24 A Uh-huh.</p>

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<p style="text-align: right;">Page 302</p> <p>1 Q Thank you, Doctor. 2 VIDEOGRAPHER: 3 Going off the record. The time is 3:33 4 p.m. 5 (OFF THE RECORD.) 6 VIDEOGRAPHER: 7 We're back on the record. The time is 8 3:48 p.m. 9 MS. BROWN: 10 Q Welcome back, Doctor. 11 Did you have an opportunity to take a 12 look if you had an earlier version of Dr. Saed's 13 manuscript? 14 A I did. 15 I did not. 16 Q Okay. And, so, during this deposition, 17 you've referred from time to time to Dr. Saed's 18 2018 paper. Is that right? 19 A (Nods affirmatively.) 20 MS. O'DELL: 21 Object to the form. Excuse me. 22 MS. BROWN: 23 Q And you received that paper after you 24 authored your report in this case; right?</p>	<p style="text-align: right;">Page 304</p> <p>1 MS. BROWN: 2 Q And if that's not the one you were 3 thinking of, Doctor, we can move on. 4 A I was thinking Henderson 1971. 5 Q And that's not an animal study; right? 6 A Maybe this -- this isn't the same one, 7 then. I can certainly find it at the end if -- 8 The -- it was a 1971 study involving a 9 rat model that the major point and conclusion of 10 the study was perhaps something that we've 11 discussed that's been now well accepted that the 12 talc can migrate, after exposure, into the 13 ovarian tissue. 14 Q Are you aware of any study, Doctor, 15 that talc on the exterior of a woman's vagina can 16 migrate up the fallopian tubes to the ovary? 17 MS. O'DELL: 18 Object to the form. 19 A I am not aware of a study that tested 20 that specifically. 21 MS. BROWN: 22 Q And did you consider, in connection 23 with your opinions here, IARC's finding that the 24 science regarding migration is, quote, "weak"?</p>
<p style="text-align: right;">Page 303</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A So I was referring -- 4 Yes. I -- I -- the manuscript we were 5 discussing was received after the completion of 6 this. But, as we discussed earlier, the 7 materials in the paper were presented in abstract 8 form or long abstract form, and those are 9 referenced in the report. 10 MS. BROWN: 11 Q And just to close the loop on one thing 12 before I hand it over to my colleague, 13 Mr. Ferguson, you had referenced an animal study 14 by Woodruff earlier in the day. Do you remember 15 that? 16 A Yes. 17 Q That paper doesn't have anything to do 18 with talc; right? 19 MS. O'DELL: 20 Object to the form. 21 A Let me -- 22 Yes, I -- you're -- the Woodruff 1979 23 paper is not the one I was -- I was wrong on the 24 author. Give me a moment to...</p>	<p style="text-align: right;">Page 305</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A My -- my primary consideration of IARC 4 was their classification of the talc and the -- 5 and the fibrous talc, and I don't recall their 6 conclusions of the migration science being weak. 7 And, in fact, it appears, as stated by 8 the FDA, that the -- the migration question is -- 9 is well resolved. 10 MS. BROWN: 11 Q Finally, Doctor, in connection with 12 your opinions in this case, did you consider 13 articles regarding whether stick lesions evidence 14 inflammation? 15 A I'd have to review some of the 16 literature for stick lesions specifically. But 17 that -- 18 Can you -- what are you referring to by 19 stick lesions? 20 Q So do you understand that it's now 21 believed, in terms of the -- where ovarian cancer 22 begins, that it begins in the fallopian tubes, 23 epithelial ovarian cancer? 24 A I certainly would agree that a -- the</p>

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<p style="text-align: right;">Page 306</p> <p>1 site of initiation, whether -- that it can begin 2 in the fallopian tubes, yes, that there's been 3 studies that have shown that evidence. 4 Q And some of the early lesions that have 5 been found in the fallopian tubes are sometimes 6 referred to as stick lesions. Are you familiar 7 with that? 8 MS. O'DELL: 9 Object to the form. 10 A I'm not. 11 MS. BROWN: 12 So you haven't looked at any studies 13 that have looked at stick lesions that have been 14 removed from women to see if there was any 15 evidence of inflammation? 16 MS. O'DELL: 17 Object to the form. 18 A That -- that -- I don't recall that as 19 part of the review. 20 MS. BROWN: 21 Q Fair enough. 22 No further questions. I'll hand it 23 over to Mr. Ferguson. 24 MR. FERGUSON:</p>	<p style="text-align: right;">Page 308</p> <p>1 the Genomic Services Laboratory -- 2 Right? There's one of those at 3 HudsonAlpha; right? 4 A There is. 5 Q Do you perform services there such as 6 running clinical samples to report results to 7 healthcare providers? Is that the kind of things 8 you do? 9 A To be -- to be clear and to, 10 importantly, differentiate the regulated lab 11 versus the research laboratory, the Genomic 12 Services Laboratory is a -- is a entity of 13 HudsonAlpha that is responsible for research 14 activities. 15 There is a separate wholly owned 16 subsidiary of HudsonAlpha creatively named the 17 Clinical Services Laboratory. So that laboratory 18 is the laboratory that performs the testing. And 19 to hopefully not provide a level of confusion, 20 but the two laboratories coexist in the same 21 space. And what this means is I have staff and 22 equipment. Some is dedicated to clinical, some 23 is dedicated to research, and some are shared 24 between the two.</p>
<p style="text-align: right;">Page 307</p> <p>1 Thank you. 2 EXAMINATION 3 BY MR. FERGUSON: 4 Q Good afternoon, Dr. Levy. My -- my 5 name is Ken Ferguson, and I represent Imerys in 6 this matter. Do you know who Imerys is? 7 A Only that they're a mining company. 8 Q Okay. And I have some questions for 9 you. I apologize for my voice. I've kind of had 10 my allergies and then going into a cold, so it's 11 kind of -- kind of stuffy. So I apologize. 12 If you have trouble hearing me or 13 understanding me, let me know. Okay? 14 A Okay. 15 Q And -- and just -- I know you've been 16 at this with Miss Brown for a little while, but 17 if there's any question that you don't understand 18 that I'm asking you, just let me know, and I'll 19 restate it so I can make sure that we're 20 communicating. Okay? 21 A Okay. 22 Q I want to talk to you, first of all, 23 about a little bit more about what you do at 24 HudsonAlpha Institute. So in the what's called</p>	<p style="text-align: right;">Page 309</p> <p>1 So, in summary, the best way to 2 consider the laboratory is that it's a clinical 3 regulated laboratory that also performs research. 4 Any projects under that research 5 umbrella are referred to as being in the Genomic 6 Services Laboratory. Anything clinical is 7 referred to the Clinical Services Laboratory. 8 That lab has been CLIA-licensed now for going on 9 five -- just past four years and has been 10 CAP-accredited for three and a half. 11 Q So is it the Clinical Services 12 Laboratory, then, that would perform services 13 like running clinical samples to get results to 14 healthcare providers? 15 A That's correct. 16 Q And -- and among those things that the 17 Clinical Services Laboratory does, is that 18 restricted to whole genome sequencing? 19 A Our currently -- the only publicly 20 disclosed and validated test for the Clinical 21 Services Laboratory is whole genome sequencing. 22 We have two other laboratory-developed 23 tests, or commonly referred to as LDTs, that are 24 run in a -- as a private assay for some clinical</p>

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<p style="text-align: right;">Page 310</p> <p>1 trials, so they're not publicly available and to</p> <p>2 date have not been publicly disclosed. They're</p> <p>3 protected under confidentiality agreement.</p> <p>4 And the Clinical Services Laboratory</p> <p>5 this year will launch a number of other tests</p> <p>6 that we have publicly disclosed. Those include</p> <p>7 whole exome sequencing, an oncology panel known</p> <p>8 as the TruSight Tumor 170, which profiles 170</p> <p>9 genes with -- that have been -- that have known</p> <p>10 involvement in cancer risk and progression, and</p> <p>11 as well as a 500 panel of similar form.</p> <p>12 Q So let me talk to you a little bit</p> <p>13 about your prior position. You were at</p> <p>14 Vanderbilt University Medical Center; correct?</p> <p>15 A Correct.</p> <p>16 Q And you were an assistant professor?</p> <p>17 Is that correct?</p> <p>18 A The titles I held there was research</p> <p>19 assistant professor and then assistant professor,</p> <p>20 and then I was a associate professor as an</p> <p>21 adjunct faculty for a number of years after</p> <p>22 joining HudsonAlpha. So I had to progress</p> <p>23 through a few of the academic ranks at</p> <p>24 Vanderbilt, but all of them in the professor</p>	<p style="text-align: right;">Page 312</p> <p>1 of pre-reviews for tenure. There were no</p> <p>2 concerns with that progress. But, based on both</p> <p>3 funding as well as publication records, I wasn't</p> <p>4 overly concerned with that.</p> <p>5 But the opportunity to be able to do --</p> <p>6 and the scale of operations at HudsonAlpha was --</p> <p>7 was too good to turn down, as far as remaining at</p> <p>8 Vanderbilt.</p> <p>9 Q So you were neither granted tenure nor</p> <p>10 denied tenure. Is that fair to say?</p> <p>11 A That's fair to say.</p> <p>12 I think the best evidence for the</p> <p>13 relationship at Vanderbilt after my leaving was I</p> <p>14 continued as an adjunct faculty in the same</p> <p>15 department, again with change in title, for a</p> <p>16 number of years after joining HudsonAlpha. So it</p> <p>17 was a -- certainly, I wouldn't characterize it as</p> <p>18 a negative departure from the institution. And I</p> <p>19 still remain a collaborator with a number of</p> <p>20 colleagues there.</p> <p>21 Q Do you have a copy of your report in</p> <p>22 front of you?</p> <p>23 A I do.</p> <p>24 Q Okay. What I'm gonna do is I'm gonna</p>
<p style="text-align: right;">Page 311</p> <p>1 realm.</p> <p>2 Q As an assistant professor, were you</p> <p>3 appointed on a tenure track?</p> <p>4 A Yes.</p> <p>5 Q And do you know generally how many</p> <p>6 years after appointment as an assistant professor</p> <p>7 is a tenure decision at Vanderbilt typically made</p> <p>8 in that department?</p> <p>9 A It varies from probably five to nine.</p> <p>10 Q Did you ever achieve tenure at</p> <p>11 Vanderbilt?</p> <p>12 A Actually, I was up for tenure the year</p> <p>13 that I moved to HudsonAlpha.</p> <p>14 Q So --</p> <p>15 A So, technically, I, which will sound</p> <p>16 odd, I was promoted to associate professor upon</p> <p>17 leaving.</p> <p>18 Q Okay.</p> <p>19 A In an adjunct role.</p> <p>20 Q So were you turned down for tenure</p> <p>21 or --</p> <p>22 A I was not. I never -- I -- the</p> <p>23 opportunity at HudsonAlpha predated the time that</p> <p>24 I would have gone up for tenure. I had a number</p>	<p style="text-align: right;">Page 313</p> <p>1 try to go through, probably in -- in order,</p> <p>2 portions of your report that I want to ask about</p> <p>3 and try to make sure I don't cover things that</p> <p>4 Miss Brown's already covered.</p> <p>5 Can you look at page 5 of your report?</p> <p>6 A Yes.</p> <p>7 Q So there -- and I'm looking at number 2</p> <p>8 on page 5, Acquired Somatic Gene Mutation.</p> <p>9 Do you see that?</p> <p>10 A I do.</p> <p>11 Q And you say there that --</p> <p>12 I'm skipping the sentences. If you</p> <p>13 need to go back, feel free.</p> <p>14 -- "Biological and lifestyle exposures,</p> <p>15 such as viruses, obesity, hormones and chronic</p> <p>16 inflammation, are also known to result in</p> <p>17 cancer-causing mutations."</p> <p>18 Right?</p> <p>19 A I see that sentence.</p> <p>20 Q Okay. Wouldn't you agree that the</p> <p>21 association between obesity and cancer risk is</p> <p>22 just that, an association and not a known</p> <p>23 cause-and-effect relationship?</p> <p>24 MS. O'DELL:</p>

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<p>1 Object to the form.</p> <p>2 A I would state that it is known that</p> <p>3 cancer rates increase in a number of unhealthy</p> <p>4 conditions, including obesity. But I am not</p> <p>5 aware of a -- of any studies that have</p> <p>6 illustrated a causal effect directly between</p> <p>7 obesity and cancer.</p> <p>8 MR. FERGUSON:</p> <p>9 Q And, specifically, isn't it true that</p> <p>10 there is no direct in vivo experimental evidence</p> <p>11 that obesity causes cancer-causing mutations?</p> <p>12 A I would have to review the literature</p> <p>13 to -- before answering that question. But the</p> <p>14 relationship between obesity and cancer risk</p> <p>15 is -- is quite well established. And I think for</p> <p>16 us to discuss that in more detail, we'd have to</p> <p>17 start delving into some of the specifics around</p> <p>18 the physiological changes related to obesity and</p> <p>19 whether those specific physiological changes play</p> <p>20 a role in cancer.</p> <p>21 Q And, just below that, the last sentence</p> <p>22 in that paragraph, you say, "These mechanisms may</p> <p>23 be direct, such as radiation directly damaging</p> <p>24 DNA, as well as indirect, such as an external</p>	<p>1 A It varies. So the -- the --</p> <p>2 "inflammatory response" is a bit general. So</p> <p>3 depending on specific type of cellular</p> <p>4 recruitment and cellular damage through the</p> <p>5 release of cytokines, the release of oxidative</p> <p>6 damaging materials from cells like granulocytes,</p> <p>7 you know, or the -- even the cell's own</p> <p>8 production of reaction to -- reactive oxygen</p> <p>9 species, such as from the mitochondria, which is</p> <p>10 the most common sync -- or most common source of</p> <p>11 reactive oxygen species in the cell.</p> <p>12 And, so, those are some examples of --</p> <p>13 of that relationship between an inflammatory</p> <p>14 response and that cellular reaction.</p> <p>15 Q Reactive oxygen species are not the</p> <p>16 same thing as inflammation; correct?</p> <p>17 A I would say reactive oxygen species are</p> <p>18 a hallmark of inflammation.</p> <p>19 Q But they're not the same thing.</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A The -- well, they are --</p> <p>23 Again, reactive oxygen species are a</p> <p>24 component of inflammation. So they're -- the</p>
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<p>1 agent causing a cellular -- cellular reaction or</p> <p>2 inflammatory response that then leads to DNA</p> <p>3 damage or mutation."</p> <p>4 What cellular reactions are you</p> <p>5 referring to that result in DNA damage or</p> <p>6 mutation?</p> <p>7 A So the presence of reactive -- so a few</p> <p>8 different things. Primarily, along the</p> <p>9 discussions for today, the presence of reactive</p> <p>10 oxygen species which can directly -- which are a</p> <p>11 cellular reaction that can then cause -- directly</p> <p>12 cause DNA damage.</p> <p>13 There's protein oxidation effects that</p> <p>14 are similar to that, in the sense that you have a</p> <p>15 chemical change and a cellular component that</p> <p>16 results in a -- in a protein activity change,</p> <p>17 again leading to potential DNA damage.</p> <p>18 And then you can have --</p> <p>19 So those are two -- two examples of</p> <p>20 cellular reactions to that.</p> <p>21 Q And -- and maybe you just explained it,</p> <p>22 but I wanted to make sure I'm clear. What is the</p> <p>23 mechanism by which an inflammatory response</p> <p>24 results in DNA damage?</p>	<p>1 words are two -- two different definitions, but</p> <p>2 they are a component.</p> <p>3 MR. FERGUSON:</p> <p>4 Q Would you agree that reactive oxygen</p> <p>5 species are a normal part of cell physiology?</p> <p>6 A Yes, absolutely.</p> <p>7 Q And the major source of reactive oxygen</p> <p>8 species comes from inside the cell and is</p> <p>9 produced in mitochondria?</p> <p>10 A A source, and depending on the site of</p> <p>11 the physiology. So a normal, healthy cell not</p> <p>12 under stress or injury would be -- then, yes,</p> <p>13 that's a true statement.</p> <p>14 Under different physiological</p> <p>15 conditions, that statement may not be true.</p> <p>16 Q Can you distinguish reactive oxygen</p> <p>17 species produced inside a cell from reactive</p> <p>18 oxygen species produced outside the cell?</p> <p>19 A What do you mean? So by -- by</p> <p>20 "distinguish," you mean --</p> <p>21 Q Can you tell the difference?</p> <p>22 A I'm just thinking if there's a way to</p> <p>23 measure.</p> <p>24 So you can measure the effects of</p>

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<p style="text-align: right;">Page 318</p> <p>1 exogenously introduced reactive oxygen species 2 and then compare that to the measurement of 3 endogenously produced reactive oxygen species. 4 But as far as determining the 5 difference if the cellular integrity is not 6 intact, I'm not aware of a method to do that. 7 Q Would you agree that generation of 8 reactive oxygen species is an inevitable 9 consequence of aging in aerobic organisms? 10 MS. O'DELL: 11 Object to the form. 12 A So reactive oxygen species are a -- 13 are present at all stages of life. And aging, as 14 a biological phenomenon, is probably one of the 15 most variable phenomenon that exists. 16 And specific to reactive oxygen 17 species, the diet, lifestyle, and genetics of 18 that individual will drastically change that. 19 And a new area of research that my 20 laboratory has been undertaking for a short 21 time -- 22 And, so, I don't have specific 23 publications, and it's really not -- I promise 24 it's not taking us too far afield.</p>	<p style="text-align: right;">Page 320</p> <p>1 would be very difficult. 2 MR. FERGUSON: 3 Q In your report, on this same page, you 4 discuss the fact that, even if someone has a 5 genetic mutation that predisposes them to cancer 6 doesn't mean that he or she is certain to get 7 cancer. Correct? 8 A That is correct. 9 Q So there is a -- a random component to 10 the effects of known cancer-causing agents. 11 Right? 12 MS. O'DELL: 13 Objection to form. 14 A There is a complicated relationship 15 between genetics, environment, and expose -- or 16 environment, including exposure and lifestyle, 17 and the progression of cancer. 18 Perhaps the -- a summary analogy is the 19 more predisposing mutations that an individual 20 has, it's -- it's equivalent to their body is 21 rolling the dice more often to collect a mutation 22 sufficient to cause cancer than somebody who does 23 not have the same genetic background. 24 And there's -- there's many, many lines</p>
<p style="text-align: right;">Page 319</p> <p>1 -- but is the concept of your annual 2 age versus biological age. And my lab has some 3 assays that are based on epigenetics as well as 4 some metabolomic markers. And what we found -- 5 now, in very, again, preliminary data -- that 6 individuals will vary by plus or minus 15 years 7 from physiological age to annual age based on, 8 again, a number of lifestyle factors not 9 important for this study. 10 But the point I'm making is the 11 discussion about level of reactive oxygen species 12 and its association with age is actually quite 13 variable based on the long -- or based on the 14 current physiological activity of that person. 15 Stated very simply, which is probably 16 something we all know, the better shape you're 17 in, the younger your physiology will appear. And 18 you can actually modulate that quite quickly, 19 meaning that a person who's 60 and has made poor 20 lifestyle choices can actually gain back quite a 21 bit of that physiological age quite quickly. 22 And so, again, to directly answer your 23 question, a annual age-related conclusion 24 regarding production of reactive oxygen species</p>	<p style="text-align: right;">Page 321</p> <p>1 of evidence. Probably the most prominent is 2 BRCA1 and 2 mutation and the role it plays in 3 increased risk of breast and ovarian cancer. 4 MR. FERGUSON: 5 Q Wouldn't you agree that even the 6 inherited susceptibility cannot entirely explain 7 this random component of some people getting 8 cancer when exposed and some people not? 9 MS. O'DELL: 10 Objection to form. 11 A DNA -- so that, it's very 12 gene-dependent. So BRCA1 and 2 is the example 13 given. That is correct, that if you have a BRCA1 14 and -- 1 or 2 mutation, you are not guaranteed to 15 get cancer. 16 Corollary to that is if you do not have 17 a BRCA1 and 2 mutation, your relative risk for 18 cancer does not change, meaning that you're at no 19 less of a risk than somebody -- somebody else who 20 doesn't have that mutation. 21 I should state that there are other 22 genes. P53 is a good example that was mentioned 23 earlier. If you carry a mutation in that gene, 24 the probability that you'll get cancer, assuming</p>

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<p style="text-align: right;">Page 322</p> <p>1 you don't die from something else, is almost</p> <p>2 certain, meaning that it's in the mid to high 90</p> <p>3 percents if you -- if you live until a late age.</p> <p>4 MR. FERGUSON:</p> <p>5 Q Further down this paragraph, you</p> <p>6 indicate that "An inherited gene mutation could</p> <p>7 instead make one more likely to develop cancer</p> <p>8 when exposed to certain cancer-causing</p> <p>9 substances."</p> <p>10 Correct? That's your statement?</p> <p>11 A Yes.</p> <p>12 Q Can you provide any examples in which a</p> <p>13 woman with an inherited mutation in a particular</p> <p>14 gene has been demonstrated to have more</p> <p>15 sensitivity to developing ovarian cancer as a</p> <p>16 result of exposure to an environmental agent?</p> <p>17 A Not for ovarian cancer specifically. I</p> <p>18 would need to review --</p> <p>19 There is a -- I've seen report of a</p> <p>20 single gene related to ovarian cancer, which,</p> <p>21 again, I would have to do a bit of searching to</p> <p>22 be sure I'm naming the correct gene, but I --</p> <p>23 where that has a much high- -- increased risk</p> <p>24 specific to ovarian cancer, but I do not recall</p>	<p style="text-align: right;">Page 324</p> <p>1 And the point of my mentioning this is</p> <p>2 to illustrate that an early predisposition to --</p> <p>3 or a significant predisposition to cancer that</p> <p>4 results in a early cancer event, those</p> <p>5 individuals show a lifetime increase in risk of</p> <p>6 approximately -- they're -- they're approximately</p> <p>7 six times, depending on the disease, to 13 times</p> <p>8 more likely to get that -- to get a secondary</p> <p>9 disease.</p> <p>10 So there clearly is a relationship to</p> <p>11 predisposition in -- in oncology -- or in rate of</p> <p>12 cancer event.</p> <p>13 Q Okay. And I appreciate your response.</p> <p>14 But remember that my question was related to</p> <p>15 ovarian cancer, and -- and we went a little</p> <p>16 afield from ovarian cancer.</p> <p>17 And I want to ask you another question</p> <p>18 in that regard. Can you provide any example in</p> <p>19 which a woman with an inherited mutation in a</p> <p>20 particular gene has been demonstrated to have</p> <p>21 more sensitivity to developing ovarian cancer as</p> <p>22 a result of exposure to talcum powder?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>
<p style="text-align: right;">Page 323</p> <p>1 if there was a measurement of any exogenous</p> <p>2 exposure risk that amplified that effect or not.</p> <p>3 But I think the -- as a general</p> <p>4 premise, it is a -- well established in cancer</p> <p>5 biology that any mu- -- any mutation that results</p> <p>6 in a burden related to DNA repair, related to</p> <p>7 cell cycle control, you are more susceptible to</p> <p>8 cancer.</p> <p>9 In one of our lines of research where</p> <p>10 we do have some publications, in pediatric</p> <p>11 cancer, I would simply point to in approximately</p> <p>12 50 percent of adults who are survivors of</p> <p>13 childhood cancer will develop a second cancer</p> <p>14 event primarily because their -- the fact that</p> <p>15 they developed a childhood cancer generally means</p> <p>16 you are predisposed to that condition.</p> <p>17 And -- and, as evidenced in the</p> <p>18 observations we've done in the analysis of</p> <p>19 thousands of patients in collaboration with</p> <p>20 St. Jude and the children's oncology group, we've</p> <p>21 identified now a ability to do genetic counseling</p> <p>22 in those individuals and predict with very high</p> <p>23 accuracy what their secondary cancer is likely to</p> <p>24 be.</p>	<p style="text-align: right;">Page 325</p> <p>1 Answer the question.</p> <p>2 A So the mechanism we proposed would be</p> <p>3 independent of -- of that predisposition. But I</p> <p>4 would have the opinion that an individual with</p> <p>5 any predisposition mutation, regardless of the</p> <p>6 gene but -- and -- in ovarian cancer, that they</p> <p>7 would be a more fragile individual as -- when it</p> <p>8 comes to this exposure under the mechanism that</p> <p>9 we've been discussing today.</p> <p>10 MR. FERGUSON:</p> <p>11 Q Okay. And what I'm looking for is some</p> <p>12 example or some literature in that regard.</p> <p>13 A I would -- I would have to -- I would</p> <p>14 have to look --</p> <p>15 Q Okay.</p> <p>16 A -- to see.</p> <p>17 Q So what you've told me is that's your</p> <p>18 opinion, but you don't have any references for it</p> <p>19 as you sit here?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to form.</p> <p>22 A So my -- what was -- I was requested to</p> <p>23 provide this biologically plausible mechanism,</p> <p>24 and part of that request was not necessarily</p>

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<p>1 include the influence on that mechanism that</p> <p>2 specific gene mutations or inherited risks may</p> <p>3 have within relation to ovarian cancer.</p> <p>4 So I'd certainly be delighted to pause</p> <p>5 for a moment and take -- you know, and -- and</p> <p>6 work on that -- give you that -- see if I can</p> <p>7 give you that specific example.</p> <p>8 MR. FERGUSON:</p> <p>9 Q But you can't as you sit here?</p> <p>10 A I cannot.</p> <p>11 Q Okay. So let's look at -- further down</p> <p>12 on page 5, you have a section entitled "The Role</p> <p>13 of Genetics in Ovarian Cancer." Correct?</p> <p>14 A Correct.</p> <p>15 Q And I want to look at a reference that</p> <p>16 you -- you have cited. And let me mark this as</p> <p>17 an exhibit, please. I guess I can mark it.</p> <p>18 (DEPOSITION EXHIBIT NUMBER 21</p> <p>19 WAS MARKED FOR IDENTIFICATION.)</p> <p>20 MR. FERGUSON:</p> <p>21 Q Exhibit 21 is the Nunes article. Have</p> <p>22 you seen that?</p> <p>23 A I have, yes.</p> <p>24 Q Okay. So if we look at page 5, at top</p>	<p>1 further and you have a sentence that starts</p> <p>2 "epithelial ovarian cancer." Correct?</p> <p>3 MS. O'DELL:</p> <p>4 On page 6 there?</p> <p>5 MR. FERGUSON:</p> <p>6 Yeah. I apologize. Yeah, it is.</p> <p>7 A Yep.</p> <p>8 MR. FERGUSON:</p> <p>9 Q It's on page 6. It's the, I believe,</p> <p>10 the last sentence of the partial paragraph at the</p> <p>11 top of 6. See it?</p> <p>12 A I do.</p> <p>13 Q Okay. And you say, "Epithelial ovarian</p> <p>14 cancer (EOC) includes most malignant ovarian</p> <p>15 neoplasms" -- you cite Chan, 2006 -- "that can be</p> <p>16 classified based on morphologic and molecular</p> <p>17 genetic features into the following types:</p> <p>18 Serous" -- and, in parentheses, "(OSC) low and</p> <p>19 high grade); endometrioid (EC), clear cell,</p> <p>20 (OCCC), and mucinous (MC) carcinomas."</p> <p>21 Correct?</p> <p>22 A Correct.</p> <p>23 Q Okay. And then if we look back at page</p> <p>24 2 of Nunes, in the second sentence of the first</p>
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<p>1 of the page, you indicate that ovarian cancer is</p> <p>2 the major cause of death from gynecologic disease</p> <p>3 and the second most common gynecologic malignancy</p> <p>4 worldwide; correct?</p> <p>5 A Correct.</p> <p>6 Q And then in your report you cite Nunes</p> <p>7 and Serpa, the article we've just marked as</p> <p>8 Exhibit 21, as well as Siegel and Torre; correct?</p> <p>9 A Yes.</p> <p>10 Q If we look at page 2 of the Nunes</p> <p>11 article, the exact same sentence appears on -- at</p> <p>12 the bottom of page 2 under the heading of</p> <p>13 "Ovarian Cancer, an Overview"; correct?</p> <p>14 A Correct.</p> <p>15 Q Right.</p> <p>16 A That's correct.</p> <p>17 Q Okay. And it's --</p> <p>18 A It's not quite the same sentence, given</p> <p>19 that it's the same initial statement, not an</p> <p>20 identical sentence.</p> <p>21 Q Very close to identical?</p> <p>22 A Well, they -- they both -- they both</p> <p>23 introduce the same facts.</p> <p>24 Q Okay. Then if we go down a little bit</p>	<p>1 paragraph under "Ovarian Cancer, an Overview,"</p> <p>2 the nearly identical sentence appears there.</p> <p>3 Correct?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A The two sentences stating the same</p> <p>7 fundamental facts regarding ovarian cancer and</p> <p>8 the histological types are -- yes, I agree.</p> <p>9 MR. FERGUSON:</p> <p>10 Q With almost the same wording.</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A They have similar wording.</p> <p>14 MR. FERGUSON:</p> <p>15 Q Remarkably similar; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A I wouldn't call it -- so they --</p> <p>19 Again, we're stating fundamental basic</p> <p>20 facts around histological type and following a</p> <p>21 number of, again, factual observations for what</p> <p>22 the state of the art for genetic knowledge</p> <p>23 in -- in different genes and different proteins</p> <p>24 is as it relates to our understanding of -- of</p>

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<p>1 cancer with, again, appropriate reference for</p> <p>2 those -- for those studies.</p> <p>3 MR. FERGUSON:</p> <p>4 Q And then if we look at the following</p> <p>5 paragraphs, the first full paragraph there on</p> <p>6 page 6, in your report you have a sentence that</p> <p>7 starts "low grade OSC cases generally have</p> <p>8 genetic alterations" in a number of items you've</p> <p>9 listed; correct?</p> <p>10 A Correct.</p> <p>11 Q Okay. And that sentence ends with the</p> <p>12 words or "p13/Ras/Notch/FOXMI." Correct?</p> <p>13 A Correct.</p> <p>14 Q Okay. And then if we go back to Nunes,</p> <p>15 if you look at that same paragraph we've been</p> <p>16 talking about -- and those -- there's an</p> <p>17 introductory phrase that you don't have, and then</p> <p>18 it starts with "low grade OSC generally</p> <p>19 comprising." Slightly different wording, but you</p> <p>20 list the same types of receptors and the same</p> <p>21 types of items. Correct?</p> <p>22 A Yes. That's providing a review of,</p> <p>23 again, the known associations between specific</p> <p>24 ovarian subtypes and their most commonly referred</p>	<p>1 MS. O'DELL:</p> <p>2 I'm sorry.</p> <p>3 MR. FERGUSON:</p> <p>4 Q -- on page 2.</p> <p>5 A Yes.</p> <p>6 MR. FERGUSON:</p> <p>7 Sorry. Leigh, it's on page -- the</p> <p>8 bottom of page 2.</p> <p>9 MS. O'DELL:</p> <p>10 Oh, I'm there. When you said the top,</p> <p>11 I got --</p> <p>12 MR. FERGUSON:</p> <p>13 No worries. That's -- my mistake.</p> <p>14 Q Okay. It says "EC subtypes," and then</p> <p>15 it goes to mucin-coding genes on the top of page</p> <p>16 3. Correct?</p> <p>17 A Correct.</p> <p>18 Q Again, that paragraph is nearly</p> <p>19 identical to the one in your report. Correct?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 MR. FERGUSON:</p> <p>23 Q Same word, same order, same citations;</p> <p>24 correct?</p>
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<p>1 genetic information or genetic predis- --</p> <p>2 sorry -- mutated genes. So I'm -- that's right.</p> <p>3 Q Okay.</p> <p>4 A They are -- they are similar in that</p> <p>5 both are, again, introducing factual information</p> <p>6 about the current knowledge in ovarian cancer in</p> <p>7 this literature, again pointing out that</p> <p>8 referencing the papers that they both came from,</p> <p>9 being the Nunes as well as the appropriate</p> <p>10 references.</p> <p>11 Q Okay. And, then, the paragraph below</p> <p>12 that starts endo- -- "endometrioid carcinoma,"</p> <p>13 paren, "(EC)." Correct?</p> <p>14 A Correct.</p> <p>15 Q If we look --</p> <p>16 And then that goes all the way to the</p> <p>17 word "mucin-coding genes" with two citations;</p> <p>18 correct?</p> <p>19 A Correct.</p> <p>20 Q If we look at 2 and the top of page 3</p> <p>21 in Nunes, there's a sentence that starts "EC."</p> <p>22 It does not spell out endometrioid carcinoma. Do</p> <p>23 you see that four lines from the top? I'm sorry.</p> <p>24 Four lines from the bottom --</p>	<p>1 MS. O'DELL:</p> <p>2 Object to the form.</p> <p>3 A So my -- my report is similar to the</p> <p>4 review article. It -- it's listing the subtypes</p> <p>5 of ovarian cancer and -- based on the Nunes</p> <p>6 paper, which is a 2018 publication, so a more</p> <p>7 current review. I'm, again, providing that</p> <p>8 referenced information about the -- the -- this</p> <p>9 observation.</p> <p>10 Q You're citing the same references as</p> <p>11 Nunes; correct?</p> <p>12 A Yes.</p> <p>13 Q You cite the -- the various gene --</p> <p>14 expression of gene in the same order they do,</p> <p>15 so --</p> <p>16 Correct?</p> <p>17 A Yes.</p> <p>18 Q And is that just coincidental? That's</p> <p>19 just happened? You happened to have put this</p> <p>20 paragraph in the same order with the same</p> <p>21 notations as -- as Nunes?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A Well, I'm listing the same information</p>

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<p style="text-align: right;">Page 334</p> <p>1 that's contained in the Nunes paper. And seeing</p> <p>2 as that -- this was a review of the literature</p> <p>3 with -- you know, based on the state of the art,</p> <p>4 the Nunes review is exactly that. And, again,</p> <p>5 I'm -- I'm repeating the information regarding</p> <p>6 the specific gene information as it relates to</p> <p>7 this -- this ovarian cancer risk and -- and --</p> <p>8 and, again, appropriately citing the basic</p> <p>9 studies as Nunes did.</p> <p>10 MR. FERGUSON:</p> <p>11 Q With virtually the same wording?</p> <p>12 A With similar wording, yes.</p> <p>13 Q Let's look at page -- page 7.</p> <p>14 MS. O'DELL:</p> <p>15 His report?</p> <p>16 MR. FERGUSON:</p> <p>17 Q Yeah. I apologize. Your report.</p> <p>18 We can set Nunes aside now.</p> <p>19 You have a paragraph starts -- that</p> <p>20 starts "individuals can inherit mutations in</p> <p>21 BRCA1, BRCA2 or p53."</p> <p>22 See it?</p> <p>23 A Uh-huh.</p> <p>24 Q And you say, "These defects allow</p>	<p style="text-align: right;">Page 336</p> <p>1 or p53 mutations can be considered causes of</p> <p>2 cancer?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A No. Not -- not specifically causal. I</p> <p>6 think the -- each of these -- as we've discussed,</p> <p>7 each of these genes, BRCA1 and BRCA2, or starting</p> <p>8 with BRCA1 and BRCA2, increase the probability of</p> <p>9 a -- of a person -- generally women -- getting</p> <p>10 breast or ovarian cancer but do not exclusively</p> <p>11 mean somebody with that mutation will get cancer.</p> <p>12 So, with that knowledge, I would not</p> <p>13 consider BRCA1 and BRCA2 mutation alone</p> <p>14 sufficient to cause cancer. It increased the</p> <p>15 risk.</p> <p>16 And, as we talked about, p53 is a bit</p> <p>17 more of a higher-risk gene, and the question as</p> <p>18 to whether or not it is possible for someone to</p> <p>19 have a -- what the rate of someone having a p53</p> <p>20 mutation and not getting cancer, I believe, is</p> <p>21 currently unknown. But there, again, is a much</p> <p>22 higher probability of developing -- developing</p> <p>23 cancer.</p> <p>24 MR. FERGUSON:</p>
<p style="text-align: right;">Page 335</p> <p>1 additional mutations to accumulate in cells and</p> <p>2 lead to a higher probability of cells being</p> <p>3 cancerous."</p> <p>4 Correct?</p> <p>5 A Correct.</p> <p>6 Q And you've indicated earlier in your</p> <p>7 report that cancer is caused by mutations.</p> <p>8 Correct?</p> <p>9 A Correct.</p> <p>10 Q And you say here that mutations in</p> <p>11 BRCA1, BRCA2 or p53 can result in the</p> <p>12 accumulation of additional mutations in cells.</p> <p>13 Correct?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A Yeah. I made the statement that BRCA1,</p> <p>17 BRCA2 and p53, they can be inherited and then, in</p> <p>18 turn, positive for those gene mutations.</p> <p>19 MR. FERGUSON:</p> <p>20 Q Okay. Would you --</p> <p>21 A So I guess if you could ask the</p> <p>22 question again to make sure I understand it.</p> <p>23 Q Well, let me -- doesn't this paragraph</p> <p>24 mean, in your comments here, that BRCA1, BRCA2,</p>	<p style="text-align: right;">Page 337</p> <p>1 Q And then the last line there of page 7,</p> <p>2 you say, "The lifetime risk for ovarian cancer is</p> <p>3 approximately 40 percent for BRCA1 carriers and</p> <p>4 15 to 20 percent for BRCA2 carriers."</p> <p>5 Correct?</p> <p>6 A Correct. Based on -- based on the</p> <p>7 study that I referenced, yes.</p> <p>8 Q Right.</p> <p>9 And -- and the -- the -- if we look at</p> <p>10 the increased risk of 40 percent as compared to</p> <p>11 the risk of cancer in the -- of ovarian cancer in</p> <p>12 the general population, that's a 25-fold increase</p> <p>13 for BRCA1 and about a 7- or 8-fold increase for</p> <p>14 BRCA2; correct?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A I -- I would have to -- to determine</p> <p>18 that. But I would say so. I'm certainly</p> <p>19 comfortable stating that the lifetime risk for</p> <p>20 ovarian cancer is approximately 40 percent. I'd</p> <p>21 have to verify your -- your math about that</p> <p>22 indicating a 25-fold increase.</p> <p>23 MR. FERGUSON:</p> <p>24 Q Do you know what the rate in the</p>

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<p>1 general population of ovarian cancer is?</p> <p>2 A It's fairly low. If I -- thinking of</p> <p>3 the cohort studies that were reviewed as part of</p> <p>4 this, it was roughly a hundred to 200 cases per</p> <p>5 30- to 40,000 women in those -- in those studies,</p> <p>6 so relatively low.</p> <p>7 Q And if we go to the top of the next</p> <p>8 page, you say -- it's page 8 -- "Therefore, the</p> <p>9 presence of mutations in the BRCA genes do not</p> <p>10 guarantee that carriers will get cancer. The</p> <p>11 presence of these mutations increases a person's</p> <p>12 risk of developing cancer when exposed to a</p> <p>13 carcinogen."</p> <p>14 Correct?</p> <p>15 A Correct.</p> <p>16 Q And you cite Park, Vitonis, and Wu for</p> <p>17 that. Is that correct?</p> <p>18 A That's correct.</p> <p>19 Q Looking at Park, isn't it true that</p> <p>20 Park does not supply any evidence to support your</p> <p>21 claim that mutations in BRCA1, BRCA2 and/or p53</p> <p>22 increase a person's risk of developing cancer</p> <p>23 when exposed to a carcinogen?</p> <p>24 A I'd have to remind myself of what's in</p>	<p>1 So the -- the Park paper does discuss</p> <p>2 the relationship of ovarian cancer risk relative</p> <p>3 to benign gynecological conditions.</p> <p>4 Q And -- and your comment that you've</p> <p>5 cited these studies for is the presence of these</p> <p>6 mutations increases a person's risk of developing</p> <p>7 cancer when exposed to a carcinogen. And these</p> <p>8 mutations would be what you've been talking about</p> <p>9 in this paragraph, the B -- the BRCA1, BRCA2, and</p> <p>10 p53; correct?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A The sentence is worded, "The presence</p> <p>14 of these mutations increases a person's risk of</p> <p>15 developing cancer when exposed to a carcinogen."</p> <p>16 MR. FERGUSON:</p> <p>17 Q Right. Right.</p> <p>18 And, for example, in Vitonis, isn't it</p> <p>19 true that BRCA1, BRCA2 and p53 were not even</p> <p>20 determined in that study and, instead, Jewish</p> <p>21 ethnicity was used as a surrogate for a woman's</p> <p>22 risk of having a mutation in one of these genes?</p> <p>23 Do you recall that --</p> <p>24 A Again, I would have --</p>
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<p>1 Park.</p> <p>2 Q Are you going through the entirety of</p> <p>3 the article?</p> <p>4 A I'm just reminding myself the content</p> <p>5 to see if I could find something that was</p> <p>6 specifically related to your question about the</p> <p>7 presence of a BRCA1 or 2 mutation.</p> <p>8 Q Okay. Is the BRCA1, BRCA2, p53, any of</p> <p>9 those even mentioned in the article?</p> <p>10 And -- and I'm not sure we'll have time</p> <p>11 for you to go through each one of them in this</p> <p>12 much --</p> <p>13 You've got -- you cited them for these</p> <p>14 propositions. I'm trying to ask you why you</p> <p>15 cited them for this proposition.</p> <p>16 A I -- I'd have to look in more detail.</p> <p>17 I don't have a specific answer regarding the --</p> <p>18 regarding BRCA1 --</p> <p>19 Q Okay.</p> <p>20 A -- I'm sorry -- BRCA genes.</p> <p>21 I would suspect the Park reference was</p> <p>22 more in the discussion of overall relative risk</p> <p>23 of developing cancer and not necessarily</p> <p>24 exclusive to the presence of a mutation.</p>	<p>1 Q -- one way or the other?</p> <p>2 MS. O'DELL:</p> <p>3 Objection.</p> <p>4 A I would have to review the -- review</p> <p>5 the paper. Because part of the review is to</p> <p>6 be -- include appropriate references with regards</p> <p>7 to ovarian cancer risk, and those may -- I think</p> <p>8 those publications provide some information in</p> <p>9 that space.</p> <p>10 MR. FERGUSON:</p> <p>11 Q All right. But when you cite studies</p> <p>12 for a statement in your report, shouldn't the</p> <p>13 studies relate to that statement?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A Well, the studies relate to a person's</p> <p>17 risk of developing cancer. But I -- I think</p> <p>18 it -- it doesn't change the accuracy of the</p> <p>19 presence of the mutation relative to that risk.</p> <p>20 But the -- I don't have a -- a good answer as far</p> <p>21 as relationship of BRCA1 and 2 to the Park paper.</p> <p>22 MR. FERGUSON:</p> <p>23 Q And -- and, then --</p> <p>24 Well, we talked about Vitonis, too.</p>

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<p style="text-align: right;">Page 342</p> <p>1 And then let's get to Wu. 2 MS. O'DELL: 3 Object to the form. You didn't comment 4 specifically about Vitonis, if you've got an 5 issue with Vitonis. You know, it's not fair to 6 assume that because I don't think you asked a 7 direct question. 8 MR. FERGUSON: 9 Okay. I thought I did, but I could be 10 mistaken. 11 MS. O'DELL: 12 You mentioned it, but I don't think 13 you -- I think it was more you rather than asking 14 a question. 15 MR. FERGUSON: 16 Q With regard to Wu, do you recall that, 17 in Wu, BRCA1, BRCA2, and p53 inherited carrier 18 mutation status were not even determined in that 19 study? Do you recall that -- 20 A The -- 21 Q -- one way or the other? 22 MS. O'DELL: 23 Object to the form. 24 A The Wu paper specifically discussed</p>	<p style="text-align: right;">Page 344</p> <p>1 syndrome patients have an increased risk of 2 cancer when exposed to a carcinogen. Correct? 3 A Correct. 4 Q What carcinogens are you referring to? 5 A I'm not -- not referring to a specific 6 carcinogen. I'm using the term "carcinogen" to 7 refer to an insult that would result in DNA 8 damage specifically because, similar to the BRCA 9 mutations, Lynch syndrome impairs DNA mismatch 10 repair. 11 So that defect alone is not sufficient 12 to result in a cellular transformation, so 13 something else has to occur. And when we 14 consider that carcinogens are -- the term 15 "carcinogen" generally refers to something that 16 has the potential to damage cellular components 17 or DNA, it's putting the -- 18 Inability to repair along with the 19 presence of a carcinogen is where that sentence 20 comes from. 21 Q So -- and I want to make sure I 22 understand what you're saying. Are you saying 23 that Lynch syndrome patients have an increased 24 risk of developing cancer after exposure to a</p>
<p style="text-align: right;">Page 343</p> <p>1 nongenetic risk factors. 2 MR. FERGUSON: 3 Q Let's go to the next paragraph, and 4 there you talk about single nucleotide variance, 5 SNVs; correct? 6 A Towards the bottom of the paragraph. 7 As -- in terms of modifiers, yes. 8 Q Yeah. Are -- are single nucleotide 9 variants mutations? 10 A Yes. 11 Q Do most SNVs result in functionally 12 defective proteins? 13 A Statistically speaking on a genome-wide 14 basis, no. 15 So a -- a single nucleotide variant is 16 a variant at any point. And if we consider 17 statistically that about 1 percent of the genome 18 encodes proteins, again, it's statistically less 19 likely that any SNV would affect a protein. 20 Q Okay. Let's look at the next 21 paragraph. There you talk about Lynch syndrome; 22 correct? 23 A Correct. 24 Q And you make a statement that Lynch</p>	<p style="text-align: right;">Page 345</p> <p>1 carcinogen, just like everyone else? 2 A No. I'm stating that Lynch syndrome -- 3 MS. O'DELL: 4 Object to the form. Excuse me. 5 A Lynch syndrome is a hereditary 6 condition that increases the overall risk of 7 cancer to an individual, similar to BRCA1 and 2 8 mutation. 9 MR. FERGUSON: 10 Q So you -- are you claiming that Lynch 11 syndrome patients have a greater increase in 12 relative risk when exposed to a particular 13 carcinogen than do people without Lynch syndrome? 14 MS. O'DELL: 15 Object to the form. 16 A No, I'm not making that statement, to a 17 specific carcinogen. 18 MR. FERGUSON: 19 Q In your next paragraph you talk of -- 20 you start with "Myriad Genetics," and you say, 21 "As with all inherited traits, a positive family 22 history is the strongest indicator of the 23 presence of genetic risk alleles in an 24 individual."</p>

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<p style="text-align: right;">Page 346</p> <p>1 Correct?</p> <p>2 A Correct.</p> <p>3 Q Isn't it true that many women who have</p> <p>4 inherited mutations like BRCA1 or BRCA2 and genes</p> <p>5 that predispose to ovarian cancer development do</p> <p>6 not have a family history of breast or ovarian</p> <p>7 cancer?</p> <p>8 A So the -- your -- your question is a</p> <p>9 little bit different than the statement. So</p> <p>10 the -- if I could clarify the statement in the</p> <p>11 report, it is more that a positive family history</p> <p>12 would be a likely indicator that someone has a</p> <p>13 genetic risk variant such as BRCA1 and 2.</p> <p>14 Q Isn't it true that family history is</p> <p>15 not a sensitive or specific indicator of</p> <p>16 whether -- of whether a particular woman has</p> <p>17 inherited a mutation in a gene associated with</p> <p>18 increased risk of ovarian cancer?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A I would say that family -- I would ask</p> <p>22 to define "sensitive" or "specific," because in</p> <p>23 genetics overall, family history remains a</p> <p>24 valuable and important characteristic in terms of</p>	<p style="text-align: right;">Page 348</p> <p>1 number higher than that if you're looking at</p> <p>2 indirect or genetic complex formation.</p> <p>3 You know, depends how far down the</p> <p>4 cellular control and signal transduction and</p> <p>5 growth and proliferation road that we go as far</p> <p>6 as how many genes. But I'm sure, as everyone</p> <p>7 well appreciates, everything in biology is</p> <p>8 interrelated in some form.</p> <p>9 And, so, it -- but I would say this</p> <p>10 statement here is that our ability to look at</p> <p>11 large-scale genetic analysis in individuals of a</p> <p>12 variety of cancer types, given the number of</p> <p>13 individuals affected by cancer and the analysis</p> <p>14 of their genetics, we've been able to identify</p> <p>15 many of -- many of the fundamental or most --</p> <p>16 perhaps most of the fundamental genes involved in</p> <p>17 that initial disease initiation or progression.</p> <p>18 It's important that it is not a</p> <p>19 comprehensive list. Hence, it is not "all," but</p> <p>20 there are a large number of genes that are well</p> <p>21 established.</p> <p>22 Q Okay. Let's look at the next page, 10.</p> <p>23 And you have a paragraph that starts</p> <p>24 "Macrophages."</p>
<p style="text-align: right;">Page 347</p> <p>1 determining the genetic component of -- of any</p> <p>2 disease, cancer included. And, so, if there's</p> <p>3 something exact regarding its sensitivity or</p> <p>4 specificity that I can comment on, I will if I</p> <p>5 know the answer. But...</p> <p>6 MR. FERGUSON:</p> <p>7 Q In -- in the top of the page -- of</p> <p>8 page 9, the next page, you indicate, "Because of</p> <p>9 the large number of individuals tested and the</p> <p>10 ability to trace their genetic inheritance, the</p> <p>11 genes involved in cancer development are well</p> <p>12 established."</p> <p>13 Is that correct?</p> <p>14 A Correct. That's what I state. I did</p> <p>15 make that statement.</p> <p>16 Q And given that they're well</p> <p>17 established, can you name all of the inherited</p> <p>18 genes that have been identified as being</p> <p>19 associated with an increased risk of ovarian</p> <p>20 cancer?</p> <p>21 A No, not -- I can't name them all off</p> <p>22 the top of my head, no. There's something in the</p> <p>23 neighborhood of 500 to -- 500 genes of strong</p> <p>24 association of cancer risk and progression, some</p>	<p style="text-align: right;">Page 349</p> <p>1 A Uh-huh.</p> <p>2 Q And the last sentence says, "Generally</p> <p>3 speaking, macrophages can increase inflammation</p> <p>4 or decrease inflammation, depending on the</p> <p>5 cytokines released."</p> <p>6 Correct?</p> <p>7 A Correct.</p> <p>8 Q So, with that statement, do you agree</p> <p>9 that inflammation can have both protumorigenic</p> <p>10 and antitumorigenic effects, depending on</p> <p>11 context, just as you state here for macrophages?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A No, I -- I would not agree with that.</p> <p>15 I -- I don't know of any evidence of that, that</p> <p>16 inflammation, as a physiological phenomenon, acts</p> <p>17 as an antitumor effect.</p> <p>18 MR. FERGUSON:</p> <p>19 Q Going to the next page, the page 11 --</p> <p>20 I'm trying to get through this</p> <p>21 hopefully within the next 15 minutes.</p> <p>22 -- under the role of inflammation in</p> <p>23 ovarian cancer --</p> <p>24 Are you with me there?</p>

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<p style="text-align: right;">Page 350</p> <p>1 A I am.</p> <p>2 Q And you're obviously talking about the</p> <p>3 role of inflammation there. Isn't it true that</p> <p>4 no published animal model has ever shown that</p> <p>5 inducing inflammation induces the development of</p> <p>6 ovarian cancer?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form.</p> <p>9 A We've been -- earlier today we were</p> <p>10 discussing some animal models as it relates to --</p> <p>11 MR. FERGUSON:</p> <p>12 Q Yeah. You and Miss Brown talked about</p> <p>13 a number of animal models.</p> <p>14 A Yeah.</p> <p>15 Q And -- and what I'm trying to ask you,</p> <p>16 is there any of those animal models or any others</p> <p>17 that have ever shown that inducing inflammation</p> <p>18 induces the development of ovarian cancer?</p> <p>19 A I didn't -- I didn't look specifically</p> <p>20 for an animal study of that type in the process</p> <p>21 of developing the report.</p> <p>22 Q Later down that page, you talk about</p> <p>23 two models. "The literature reviews as well as</p> <p>24 many direct studies feature the immune system as</p>	<p style="text-align: right;">Page 352</p> <p>1 anything on that, so that's -- that's fine.</p> <p>2 Let's move on.</p> <p>3 A Okay.</p> <p>4 Q I think you've stated earlier that your</p> <p>5 opinion in this case is based on the totality of</p> <p>6 what is included in the product, the talcum</p> <p>7 powder products. Is that correct?</p> <p>8 A Correct.</p> <p>9 Q So you're -- you cannot distinguish</p> <p>10 the -- the carcinogenicity of the constituent</p> <p>11 parts of the talcum powder products, correct,</p> <p>12 including the fragrance?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form.</p> <p>15 A I -- I was -- I was not asked to -- to</p> <p>16 provide that delineation. And, so, instead,</p> <p>17 subsequent to seeing some of the other expert</p> <p>18 reports, we began with talcum powder as a product</p> <p>19 and then have since learned more about the</p> <p>20 constituent components, including asbestos,</p> <p>21 fragrance, potential for heavy metals, which I</p> <p>22 understand or I've observed that there's a</p> <p>23 variety of testing documents that -- that show a</p> <p>24 variety of results.</p>
<p style="text-align: right;">Page 351</p> <p>1 being an important mediator of ovarian</p> <p>2 carcinogenesis via two models, chronic</p> <p>3 inflammation and incessant ovulation."</p> <p>4 Correct?</p> <p>5 A Correct.</p> <p>6 Q Is it your opinion that incessant</p> <p>7 ovulation is a form of chronic inflammation?</p> <p>8 A It is not.</p> <p>9 Q Isn't it true that there's no</p> <p>10 pathological evidence in humans that perineal</p> <p>11 talc users have ovarian inflammation?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A I'm thinking.</p> <p>15 I would have to review the --</p> <p>16 I'm sorry. That's -- it's --</p> <p>17 MR. FERGUSON:</p> <p>18 Q Okay.</p> <p>19 A I would -- again, I would have to look</p> <p>20 more carefully for that. I can't -- I can't name</p> <p>21 a study of that type right now.</p> <p>22 Q So I think you've said previously --</p> <p>23 Are you done looking?</p> <p>24 I understood you couldn't give me</p>	<p style="text-align: right;">Page 353</p> <p>1 So, to answer your question, I did not</p> <p>2 specifically evaluate the individual specific</p> <p>3 components in any -- in any individual product as</p> <p>4 it relates. Instead, remained focused on the</p> <p>5 mechanism for the complete -- complete product.</p> <p>6 MR. FERGUSON:</p> <p>7 Q And you've made reference to heavy</p> <p>8 metals throughout your testimony on occasion. Do</p> <p>9 you recall that?</p> <p>10 A I do.</p> <p>11 Q Do you have any opinions that any of</p> <p>12 these heavy metals contribute to the inflammation</p> <p>13 process that you've been talking about?</p> <p>14 A The -- to the inflammation --</p> <p>15 I'm not aware of any direct evidence</p> <p>16 for heavy metal contribution to the inflammation</p> <p>17 process that we've been discussing. Instead, the</p> <p>18 heavy metals, particularly chromium, caught my</p> <p>19 attention because of its well-established ability</p> <p>20 to directly damage DNA and, therefore, you know,</p> <p>21 potentially play a role in carcinogenesis.</p> <p>22 Q Do you have any knowledge or opinion</p> <p>23 about how much chromium you claim is in the -- in</p> <p>24 the body powder products?</p>

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<p style="text-align: right;">Page 354</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A I wasn't asked to evaluate the amount 4 of chromium or whether it was sufficient for 5 damage. It was more reviewing. I would have to 6 defer to other experts who have done the testing 7 on the products. 8 MR. FERGUSON: 9 Q So you have no opinion on that? 10 MS. O'DELL: 11 Object to the form. 12 A I'm sorry. An opinion on the amount of 13 chromium? 14 MR. FERGUSON: 15 Q Correct. 16 A Again, I wasn't asked to generate such 17 an opinion. 18 Q I think -- I think I'm almost done. 19 Isn't it true that published data have 20 demonstrated that talc is not genotoxic and does 21 not cause mutations? 22 MS. O'DELL: 23 Object to the form. 24 A I'm not aware of a study that</p>	<p style="text-align: right;">Page 356</p> <p>1 talc with asbestiform bodies, I think would be 2 very reasonable to state that it has mutagenic 3 properties. 4 MR. FERGUSON: 5 Q And can you cite me any literature for 6 that? 7 A I would simply refer to the -- much of 8 the body of asbestos literature for the -- for 9 that. 10 MR. FERGUSON: 11 I think that's all I have. I'll turn 12 it over to someone else to ask some questions. 13 MS. BROWN: 14 Anybody with some more? 15 MS. O'DELL: 16 I'm going to take a break for a few 17 minutes. 18 VIDEOGRAPHER: 19 Going off the record. The time is 20 4:54 p.m. 21 (OFF THE RECORD.) 22 VIDEOGRAPHER: 23 We're back on the record. The time is 24 5:20 p.m.</p>
<p style="text-align: right;">Page 355</p> <p>1 specifically looked at the genotoxicity of -- of 2 talc. And I think it would certainly warrant 3 defining which type of talc and components 4 therein. But I'm -- I'm not aware of a study 5 that has concluded that there are no genotoxic 6 effects of any type of talc. 7 MR. FERGUSON: 8 Q Would you agree there's no evidence 9 that talc causes sister chromatid exchange or 10 unscheduled DNA synthesis? 11 MS. O'DELL: 12 Object to the form. 13 A I didn't -- I didn't review the 14 literature for those two specific phenomenon. I 15 would have to, again, specifically look or review 16 for that. 17 MR. FERGUSON: 18 Q So, as you sit here, you have no 19 opinion as to whether talc is or is not 20 mutagenic? 21 MS. O'DELL: 22 Object to the form. 23 A No. We've -- so talc in general, 24 particularly in its -- in its form of fibrous</p>	<p style="text-align: right;">Page 357</p> <p>1 EXAMINATION 2 BY MS. O'DELL: 3 Q Dr. Levy, I have just a few follow-up 4 questions for you. 5 I'm gonna ask you to turn to page 14 of 6 your report. 7 And earlier today -- 8 I'm going to ask, Doctor, if you could 9 put the exhibits in front of you, and we'll pull 10 those out. 11 But earlier today you were asked about 12 a letter from the FDA that was marked as Exhibit 13 Number 16, and if you could pull that out of your 14 stack there. And, specifically, if you'll turn 15 to page 4 of the letter. 16 And you'll recall that this letter was 17 written in 2014. Do you remember that? 18 A Yes. 19 Q And if you look, however, at page 4 of 20 the letter, it appears that the FDA's review of 21 the relevant toxicity literature stopped at the 22 year 2008. Fair? 23 MS. BROWN: 24 Objection to the form.</p>

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<p style="text-align: right;">Page 358</p> <p>1 MS. O'DELL: 2 Q Did the FDA's review of the toxicity 3 literature stop in 2008? 4 A Yes. 5 Q And if you look at page 14 of -- of 6 your report, your review of the literature 7 included multiple references that were published 8 after 2008? 9 MS. BROWN: 10 Form. 11 A That's correct. 12 MS. O'DELL: 13 Q And, in fact, you cited Shukla that was 14 published in -- 15 Was Shukla published in 2009? 16 A Yes. The reference is in the report to 17 2009. 18 Q Yes. 19 And, in addition to that, did you cite 20 other references in support of your opinion that 21 talc powder causes inflammation that were dated 22 and published after 2008? 23 A I did. 24 Q And, so, the suggestion by counsel for</p>	<p style="text-align: right;">Page 360</p> <p>1 Objection to the form of the question. 2 A Yes, we -- we had a discussion 3 regarding the results shown in Figure 3, the 4 level of exposure of talc as well as its 5 duration. Sorry. The talc dose as well as 6 duration. 7 MS. O'DELL: 8 Q And in the -- if you'll look at 9 Figure 1, Doctor, explain to us, please, what 10 Figure 1 describes in terms of the viability of 11 the cells at the 72-hour mark. 12 A So the -- so Figure 1 is a graph 13 describing percent cell viability versus the 14 different normal or variant cells at a 24-hour 15 and 72-hour time point, two different ovarian 16 cancer cell lines, as well as doses of talc from 17 zero micrograms per milliliter up to 500 18 micrograms per milliliter, and each of those is 19 applied. 20 And at the 72-hour time point in both 21 cell lines, OSE2a and GCA1 -- GC1a shows a 22 decrease in cellular viability that is 23 dose-dependent in each of the four cell lines. 24 Q Okay. And --</p>
<p style="text-align: right;">Page 359</p> <p>1 Johnson & Johnson that somehow the FDA had 2 reviewed the literature for toxicity up until the 3 date of this letter would have been incorrect? 4 MS. BROWN: 5 Objection to the form of the question. 6 A As -- as we discussed, the -- the 7 letter from the FDA dated April 1st, 2014, states 8 to include literature from 1980 to 2008. 9 MS. O'DELL: 10 Q Let me ask you -- 11 You can put that aside, Dr. Levy. 12 Thank you. 13 And I want to ask you to pull out of 14 the stack the Exhibit 17, which is the Buz'Zard 15 paper. 16 A I have it. 17 Q And if you'll turn to page 581. 18 A Okay. 19 Q And just to orient our discussion, 20 counsel for Johnson & Johnson suggested that -- 21 that this paper showed a decrease in reaction or 22 reactive oxygen species at the longest time 23 interval. Do you recall that discussion? 24 MS. BROWN:</p>	<p style="text-align: right;">Page 361</p> <p>1 A Sorry. Each of the two cell lines. 2 Q And is it fair to say that the reason 3 you don't see dose response, you know, at the -- 4 at the greatest magnitude is because the cells 5 essentially die? 6 MS. BROWN: 7 Objection to the form. 8 A Well, I would say if we consider the 9 results displayed in Figure 1 in relation to the 10 results displayed in Figure 3, an ex- -- an 11 explanation for the concentrating on the 500 -- 12 the highest dose, the 500 micrograms per 13 milliliter, in the talc exposure, the decrease in 14 cellular viability is an -- is an explanation -- 15 could be an explanation for the decrease in 16 reactive oxygen species. 17 MS. O'DELL: 18 Q Okay. Thank you, Doctor. 19 And if you'll put that aside and turn 20 to Exhibit 7, which was the Hamilton paper we 21 spent quite a lot of time on earlier. 22 Do you recall the -- that discussion 23 regarding the Hamilton paper? 24 A I do.</p>

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<p>1 Q And what was the purpose for which you</p> <p>2 cited the Hamilton paper?</p> <p>3 A That it was one of the available animal</p> <p>4 studies looking at the effects of talc on a rat</p> <p>5 ovary.</p> <p>6 Q And did the paper show that there was a</p> <p>7 increase in inflammation as result of talc?</p> <p>8 A Yes, in the form of foreign body</p> <p>9 granulomas observed in five of the injected</p> <p>10 ovaries.</p> <p>11 Q And you're looking at, I guess, that</p> <p>12 last sentence on page 103 and carrying over to</p> <p>13 the -- to the narrative on page 105?</p> <p>14 A Cellular foreign body?</p> <p>15 Q Yes.</p> <p>16 A Foreign body granulomas without any</p> <p>17 surrounding inflammation were seen in five of the</p> <p>18 injected ovaries. And similar lesions were not</p> <p>19 uncommonly noted in the supracapsular fat in the</p> <p>20 connective tissue matrix of the capsule.</p> <p>21 Q And if you'll look down in the</p> <p>22 discussion section, Dr. Levy, the first paragraph</p> <p>23 there in your -- where -- beginning</p> <p>24 "Unfortunately," does it appear that talc also</p>	<p>1 principle been published in the peer-reviewed</p> <p>2 literature?</p> <p>3 A It has.</p> <p>4 Q And, in regard to ovarian cancer, prior</p> <p>5 to becoming involved in the litigation, did you</p> <p>6 hold the opinion that inflammation was a part of</p> <p>7 the development of ovarian cancer?</p> <p>8 A Yes.</p> <p>9 Q And has that been researched and that</p> <p>10 research published in the peer-reviewed</p> <p>11 literature?</p> <p>12 A It has.</p> <p>13 Q In the same way, has the fact that</p> <p>14 talc, talcum powder, induces inflammation been</p> <p>15 published in the peer-reviewed literature?</p> <p>16 MS. BROWN:</p> <p>17 Objection to the form.</p> <p>18 A Yes.</p> <p>19 MS. O'DELL:</p> <p>20 Q And you were asked whether there was</p> <p>21 evidence that talc caused inflammation in humans.</p> <p>22 Do you recall that question?</p> <p>23 A I do.</p> <p>24 Q And based on your exhaustive review of</p>
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<p>1 induced fibrosis --</p> <p>2 MS. BROWN:</p> <p>3 Objection to form.</p> <p>4 MS. O'DELL:</p> <p>5 Q -- in the rats?</p> <p>6 A The manuscript makes the statement</p> <p>7 that, "Unfortunately, bursal distention occurred</p> <p>8 as an unforeseen complication" and further states</p> <p>9 that this probably resulted from talc-induced</p> <p>10 fibrosis and obliteration of the small channel</p> <p>11 which normally allows communication between the</p> <p>12 cavity where the ovary lies and the perineum.</p> <p>13 Q And though the authors concluded that</p> <p>14 neoplastic changes were not seen, the authors did</p> <p>15 find evidence of inflammation in their study?</p> <p>16 A That's correct.</p> <p>17 Q Prior to becoming involved in the</p> <p>18 litigation, Dr. Levy, did you hold the opinion</p> <p>19 that inflammation is a cause of cancer?</p> <p>20 A As -- as we've discussed earlier, I</p> <p>21 certainly held the opinion that, you know,</p> <p>22 inflammation is a significant and necessary</p> <p>23 component of cancer progression.</p> <p>24 Q And has that been -- that general</p>	<p>1 the literature, what evidence would you point to</p> <p>2 undergirding your opinion that talc causes</p> <p>3 inflammation in humans?</p> <p>4 A I think considering the molecular</p> <p>5 mechanism we were discussing of the recent paper</p> <p>6 by Saed, et al., again, that we discussed earlier</p> <p>7 today is a fairly in-depth set of experiments to</p> <p>8 examine the specific inflammatory response</p> <p>9 of -- of human cells to -- to talcum powder.</p> <p>10 Q In addition to the Saed publications,</p> <p>11 would you -- would you include the Shukla 2009</p> <p>12 paper in your consideration of talc causing</p> <p>13 inflammation in humans?</p> <p>14 A Yes.</p> <p>15 MS. BROWN:</p> <p>16 Form.</p> <p>17 MS. O'DELL:</p> <p>18 Q You were asked about your methodology</p> <p>19 numerous times today, and can -- would you</p> <p>20 describe in -- in general the methodology you</p> <p>21 have used in reaching your opinions in this case?</p> <p>22 A Yes. To clarify or perhaps expand on</p> <p>23 the earlier discussions, my methodology involved</p> <p>24 a literature review to examine the totality of</p>

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<p style="text-align: right;">Page 366</p> <p>1 the information available to the role that talcum 2 powder plays in inflammation in ovarian cancer. 3 And, so, that methodology involved, 4 first, a review of the literature and then a 5 development of a report and then a synthesis of a 6 biologically plausible mechanism where the basis 7 of that plausibility was to ask if each of the 8 different component steps that are described in 9 that mechanism was supported by peer-reviewed 10 research. First, does talc cause inflammation? 11 Second, does inflammation cause cancer? And 12 then, third -- or does inflammation cause ovarian 13 cancer? And then, third, is there -- is that 14 supportive of a overall mechanism of cancer 15 progression and metastasis? 16 Q Can that methodology be replicated? 17 A Certainly. I think, you know, anyone 18 with a similar -- similar background and 19 experience who -- who undertook the same 20 activities would likely -- certainly likely come 21 up with the same -- same conclusions. 22 Q Did you rely on the IARC monograph in 23 relation to nickel, chromium, and cobalt in 24 reaching your opinions in this case?</p>	<p style="text-align: right;">Page 368</p> <p>1 Q Is this the Park paper that you 2 referenced -- 3 MS. BROWN: 4 Counsel, do you have a copy for us? 5 MS. O'DELL: 6 I don't. I'm assuming -- I don't think 7 Ken marked it, but I'm assuming he has a copy. 8 Q Is that the Park paper that you 9 referenced in your report, Dr. Levy? 10 A It is. 11 Q And if you'll turn to page 8 of the 12 paper, about midway down the first column, maybe 13 a little bit less, see the paragraph starting "We 14 did find an association"? Page 8. 15 A I'm looking for the page number. 16 Q Sorry. Let me give you a page number. 17 I'm not sure it has a page number. 18 A No, it doesn't. 19 Q Do you see the paragraph beginning "We 20 did find associations between overall cancer and 21 history of fibroid or ovarian cysts"? Do you see 22 that paragraph? 23 A Well, actually -- yes, I see that 24 paragraph.</p>
<p style="text-align: right;">Page 367</p> <p>1 MS. BROWN: 2 Objection to the form. 3 A I -- so the -- the number of IARC 4 publications were certainly in the material that 5 was reviewed for -- for my -- for my report. 6 MS. O'DELL: 7 Q Based on your review of the literature, 8 is it your opinion that nickel causes 9 inflammation? 10 A Yes. The IARC -- the -- the 11 characterization of those compounds, nickel as 12 well as chromium, among others, are -- would have 13 an inflammatory response. 14 Q You were asked questions earlier 15 today -- actually, not so much earlier -- a few 16 minutes ago regarding the Park paper. And you 17 cited the Park paper on page -- I think it was 8 18 of your report. 19 A Yes. 20 Q And let me show you what I'm marking as 21 Exhibit 22 to your deposition. 22 (DEPOSITION EXHIBIT NUMBER 22 23 WAS MARKED FOR IDENTIFICATION.) 24 MS. O'DELL:</p>	<p style="text-align: right;">Page 369</p> <p>1 Q If you'll look further, the sentence 2 beginning "This observation may suggest," do you 3 see that? 4 A Yes. Uh-huh. 5 Q And the paper says, "This observation 6 may suggest a possible additive or synergistic 7 effect on tumor- -- tumorigenesis influenced by 8 the proinflammatory milieu from an increased 9 burden in the number of benign conditions. 10 Increased risk of serous cancer, ovarian cancer, 11 women with other proinflammatory risk factors has 12 been reported -- reported, most notably in talc 13 users." 14 Do you see that? 15 A I do. 16 Q Is that the section you were thinking 17 of when you cited it in your report? 18 MS. BROWN: 19 Objection to the form. 20 A Yes, it is. 21 MS. O'DELL: 22 Q Let me ask you to -- a couple of other 23 final questions, Dr. Levy. 24 Excuse me. Give me one moment.</p>

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<p>1 In regard to opinions in relation to</p> <p>2 the pathology of ovarian tissue, would you defer</p> <p>3 to a gynecologist or gynecologic oncologist or a</p> <p>4 pathologist regarding that matter?</p> <p>5 A Yes, of course.</p> <p>6 Q You testified earlier today that you</p> <p>7 relied on the Longo testing in -- in reaching</p> <p>8 your opinions in this case.</p> <p>9 MS. BROWN:</p> <p>10 Objection to the form.</p> <p>11 MS. O'DELL:</p> <p>12 Q Did you rely on Dr. Longo's testing</p> <p>13 in -- in reaching your opinions in this case?</p> <p>14 A Yes. They were -- they were one of</p> <p>15 the -- among many of the manuscripts we've been</p> <p>16 discussing.</p> <p>17 Q Yeah.</p> <p>18 In fact, you cite Dr. Longo's report on</p> <p>19 page 15 of your report. Is that right?</p> <p>20 MS. BROWN:</p> <p>21 Objection to the form.</p> <p>22 A Yes.</p> <p>23 MS. O'DELL:</p> <p>24 Q And -- and in terms of Dr. Longo's</p>	<p>1 Q And did you have the opportunity to</p> <p>2 consider his report prior to finalizing your</p> <p>3 report?</p> <p>4 A I did.</p> <p>5 Q I have nothing further. Thank you.</p> <p>6 EXAMINATION</p> <p>7 BY MS. BROWN:</p> <p>8 Q Dr. Levy, would you take Exhibit 16</p> <p>9 out, please, the FDA's response to the citizens</p> <p>10 petition?</p> <p>11 A I have it.</p> <p>12 Q Counsel asked you some questions that</p> <p>13 involved questions that I asked you. Remember</p> <p>14 she asked you the lawyer for J & J didn't point</p> <p>15 out the articles that were reviewed from 1980 to</p> <p>16 2008 on page 4? Do you recall those questions</p> <p>17 from plaintiffs' counsel?</p> <p>18 A Yes.</p> <p>19 Q Would you look at the last page of the</p> <p>20 letter, page 6 of 7? I'd like to direct your</p> <p>21 attention to the second sentence on this page</p> <p>22 that begins "In consideration of your request."</p> <p>23 Do you see that?</p> <p>24 A I do.</p>
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<p>1 report, his findings of 37 of 56 historical talc</p> <p>2 samples being positive for asbestos and 41 of the</p> <p>3 42 samples tested containing fibrous talc,</p> <p>4 was -- was that information you had prior to</p> <p>5 reaching your opinions and finalizing your</p> <p>6 report?</p> <p>7 MS. BROWN:</p> <p>8 Objection to the form.</p> <p>9 A Yes.</p> <p>10 MS. O'DELL:</p> <p>11 Q And in relation to Dr. Crowley's report</p> <p>12 regarding the fragrance chemicals, do you defer</p> <p>13 to Dr. Crowley regarding his analysis of the</p> <p>14 fragrance chemicals?</p> <p>15 A Yes.</p> <p>16 Q And did you rely on the opinions he</p> <p>17 reached in relation to the fragrance chemicals in</p> <p>18 reaching your opinions in this case?</p> <p>19 A Yes. My -- my review of that just, in</p> <p>20 addition to deferring it, was -- just made the</p> <p>21 general -- or made the statement that I was in</p> <p>22 general agreement with his opinions in those</p> <p>23 matters, seeing as that's not a -- not an area of</p> <p>24 expertise of mine.</p>	<p>1 Q And it states, "In consideration of</p> <p>2 your request, we conducted an expanded literature</p> <p>3 search dating from the filing of the petition in</p> <p>4 2008 through January 2014. The results of this</p> <p>5 search failed to identify any new compelling</p> <p>6 literature data or new scientific data."</p> <p>7 Do you see that?</p> <p>8 A I see that.</p> <p>9 Q And putting together, then, the</p> <p>10 information from page 4 and page 6, you see that</p> <p>11 the FDA considered literature from 1980 to 2014.</p> <p>12 Is that correct?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form.</p> <p>15 A Yes, that is correct.</p> <p>16 MS. BROWN:</p> <p>17 Q And what the FDA concluded, contrary to</p> <p>18 your opinion here, Doctor, is that a cogent</p> <p>19 biological mechanism by which talc might lead to</p> <p>20 ovarian cancer is lacking; correct?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A That's in this --</p> <p>24 MS. BROWN:</p>

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<p style="text-align: right;">Page 374</p> <p>1 Q Directing your attention to page 4, 2 number 4, the conclusion regarding a cogent 3 biological mechanism lacking. Do you see that? 4 MS. O'DELL: 5 Object to the form. 6 A Yes. I see where they -- they made the 7 statement that cogent biological mechanism by 8 which talc might lead to ovarian cancer is 9 lacking and that exposure to talc does not 10 account for all cases of ovarian cancer. 11 MS. BROWN: 12 Q Next, Doctor, do you rely on the 13 findings of the Hamilton article in forming your 14 opinions in this case? 15 A Similar to as we've discussed, in a 16 portion, yes. 17 Q You, Dr. Levy, cannot point us to a 18 single paper showing an inflammatory response 19 leading to ovarian cancer in humans from talc 20 use. True? 21 A There is -- I do not know of a single 22 paper that -- in a controlled fashion in humans 23 provided talc exposure that then was -- 24 subsequently led to cancer in humans. That's</p>	<p style="text-align: right;">Page 376</p> <p>1 talc was causing in the body. True? 2 MS. O'DELL: 3 Object to the form. 4 A I'm aware of a number of studies that 5 looked at inflammatory response in model systems 6 and cell lines, and additional studies that 7 looked at inflammation in humans I believe were 8 referenced. 9 Certainly the Penninkilampi manuscripts 10 described inflammatory observations and -- as 11 well as the Buz'Zard and Lau were on human cells. 12 Q Dr. Levy, is it your testimony that the 13 Penninkilampi meta-analysis of prior 14 case-controlled studies demonstrated a 15 inflammatory response of -- from perineal use of 16 talc that led to ovarian cancer? 17 MS. O'DELL: 18 Object to the form. 19 A No. That's not my statement. It was 20 that those -- those papers reported an 21 inflammatory observation as part of those 22 studies. 23 MS. BROWN: 24 Q Not in the tissue from talc; right,</p>
<p style="text-align: right;">Page 375</p> <p>1 correct. 2 Q Controlled aside, you're not aware of 3 any observational case report, any kind of study 4 that shows talcum powder use causing an 5 inflammatory response leading to cancer in 6 humans; correct? 7 MS. O'DELL: 8 Object to the form. 9 A I would -- my review and development of 10 the biological plausibly -- plausible mechanism 11 examined literature that led to the conclusions 12 described in the report. I'm not aware of a -- 13 The human-based studies were all case 14 cohort and -- or case-controlled and cohort 15 studies that showed an association with talc 16 exposure and cancer, but I'm not aware of a 17 direct study. 18 MS. BROWN: 19 Q There have been some reports of alleged 20 findings of talc in tissues or in other parts of 21 the body. Are you familiar with those? 22 A Yes. 23 Q And you're not aware of any one of them 24 demonstrating an inflammatory response that the</p>	<p style="text-align: right;">Page 377</p> <p>1 Doctor? 2 MS. O'DELL: 3 Object to the form. 4 A It would be those studies in the meta 5 review were not examining the tissue content for 6 talc. So they're unable to make that 7 determination. 8 MS. BROWN: 9 Q So we must be missing. I'm -- what I'm 10 asking you is for any study at all in the whole 11 world that shows that talcum powder in somebody's 12 body causing an inflammatory response that led to 13 ovarian cancer. Can you name one? 14 MS. O'DELL: 15 Object to the form. 16 A I mean, we've -- we've discussed a 17 number of studies that described the risk and 18 association of talc in ovarian cancer. But the 19 limitation of the -- of your question or the 20 limitation of the studies relative to your 21 question is those particular studies may not have 22 also assessed the inflammatory response or an 23 inflammatory response, given the nature of the 24 studies.</p>

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<p style="text-align: right;">Page 378</p> <p>1 MS. BROWN: 2 Q Well, we got one. We got the Heller 3 study that purported to find talc in ovarian 4 tissue; right? 5 MS. O'DELL: 6 Object to the form. Different -- 7 MS. BROWN: 8 Counsel, it's form, please. 9 MS. O'DELL: 10 Object to the form. 11 A Yeah. What was the -- the Heller 12 study, here it is. 13 Yes, I recall our discussion of this 14 paper. 15 MS. BROWN: 16 Q Right. 17 And this study reported that there was 18 no inflammatory response around the talc that 19 they claimed to have found in the ovarian tissue. 20 True? 21 A They make those statements in the 22 paper, but the -- the -- I would have some 23 concern with the histological methods, but I 24 would certainly defer to a pathologist in the</p>	<p style="text-align: right;">Page 380</p> <p>1 MS. O'DELL: 2 Actually, that wasn't your question. 3 But you've clarified it, so -- 4 A The -- so you're excluding -- are you 5 excluding cell lines? 6 MS. BROWN: 7 Q Yeah. Human beings. Do you know of 8 any study like Heller in human beings that 9 purports to find talc in human women ovarian 10 tissue that shows an inflammatory response? 11 MS. O'DELL: 12 Objection to form. 13 A I'm not aware of a study showing that 14 specifically. 15 MS. BROWN: 16 Q Counsel asked you some questions about 17 nickel causing inflammation that leads to ovarian 18 cancer. Do you recall those? 19 MS. O'DELL: 20 Object to the form. 21 A No. I was asked if -- if heavy 22 metal -- or components like nickel have been 23 shown to have a potential inflammatory response. 24 MS. BROWN:</p>
<p style="text-align: right;">Page 379</p> <p>1 sense of being able to determine the both 2 presence of talc and the inflammatory response in 3 that. 4 Q So you have some critiques of the 5 Heller study. Is that fair? 6 MS. O'DELL: 7 Object to the form. 8 A I would say I would need a -- I would 9 need a -- a -- I would need a further evaluation 10 of the methodology for detecting both talc as 11 well as inflammation in the same materials using 12 the methods of the Heller paper. 13 MS. BROWN: 14 Q Are you aware of any other paper that 15 you think is methodologically superior that shows 16 the presence of talc in ovarian tissue exhibiting 17 an inflammatory response? 18 MS. O'DELL: 19 Object to the form. 20 A Well, we've discussed the rat studies. 21 MS. BROWN: 22 Q Human tissue. That's my question. 23 A Human -- 24 Q Human tissue.</p>	<p style="text-align: right;">Page 381</p> <p>1 Q Uh-huh. Because you're not aware of 2 any published scientific literature that shows 3 heavy metals cause inflamma- -- inflammation that 4 leads to ovarian cancer; right? 5 A I wasn't asked to -- to review for 6 that. I would state that there's a number of 7 studies that show the role of metals -- 8 particularly chromium -- and its -- and its 9 damaging effect on DNA, which I think by -- would 10 certainly have both an inflammatory as well as 11 carcinogenic effect. 12 Q And we're here on an issue of ovarian 13 cancer. And, as it relates to ovarian cancer, 14 you're not aware of any scientific support for 15 the proposition that heavy metals can lead to 16 inflammation that causes ovarian cancer. Fair 17 enough? 18 A Well, I was -- certainly, I was asked 19 to review the literature to develop a -- and 20 develop conclusions of that literature as it 21 related to a -- a potential or possible 22 biological mechanism. 23 In doing that, in part of that review, 24 we certainly made the observation that talc and</p>

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<p style="text-align: right;">Page 382</p> <p>1 its components, as we discussed earlier, may</p> <p>2 have -- there's the possibility of having</p> <p>3 additional component effects, such as heavy</p> <p>4 metals and their effects, asbestiforms and their</p> <p>5 effects and the like; therefore, really</p> <p>6 considering the complete components of the</p> <p>7 product overall.</p> <p>8 Q And, as it relates to the testimony you</p> <p>9 just gave, you're talking about just a</p> <p>10 theoretical possibility; right?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A Sure. And, then, from that review</p> <p>14 developing a -- a conclusion of a biologically</p> <p>15 plausible mechanism.</p> <p>16 MS. BROWN:</p> <p>17 Q Has that conclusion been published in</p> <p>18 the peer-reviewed literature, Doctor?</p> <p>19 A No, it has not.</p> <p>20 Q And, in fact, as you -- all of the</p> <p>21 opinions that you gave here today, those opinions</p> <p>22 have not been published in the peer review</p> <p>23 literature. True?</p> <p>24 MS. O'DELL:</p>	<p style="text-align: right;">Page 384</p> <p>1 mineralogy of talc.</p> <p>2 Q And whether what Dr. Longo is finding</p> <p>3 in the samples that he tested is the asbestiform</p> <p>4 or nonasbestiform variety of the minerals, you</p> <p>5 would defer to others? Is that fair?</p> <p>6 A I'd certainly defer to Dr. Longo.</p> <p>7 Q And have you looked at any other</p> <p>8 testing of the samples that Dr. Longo has tested?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form. Vague.</p> <p>11 A Within the literature, there's -- there</p> <p>12 was a number of tables describing testing,</p> <p>13 described tests from previous testimony.</p> <p>14 MS. BROWN:</p> <p>15 Q Have you looked at the testing that</p> <p>16 public health authorities like the FDA have done</p> <p>17 on Johnson & Johnson's baby powder?</p> <p>18 A I believe some of that was provided,</p> <p>19 yes.</p> <p>20 Q Are you relying on any finding of</p> <p>21 asbestos from Dr. Longo in forming your opinions</p> <p>22 here today?</p> <p>23 A The --</p> <p>24 MS. O'DELL:</p>
<p style="text-align: right;">Page 383</p> <p>1 Object to the form.</p> <p>2 A Not at this time.</p> <p>3 Q Counsel asked you some questions about</p> <p>4 Dr. Longo. Do you recall that?</p> <p>5 A Yes.</p> <p>6 Q You've done nothing to validate the</p> <p>7 findings that Dr. Longo writes about in his</p> <p>8 reports. Is that fair?</p> <p>9 A No, I have not done any experiments to</p> <p>10 validate those findings.</p> <p>11 Q Okay. Are you aware that some of the</p> <p>12 samples that Dr. Longo tests and purports to find</p> <p>13 asbestos were purchased off of eBay?</p> <p>14 MS. O'DELL:</p> <p>15 Misstates -- well --</p> <p>16 A My review of the report, I was -- did</p> <p>17 not include the -- I guess the specific history</p> <p>18 of each of the samples.</p> <p>19 MS. BROWN:</p> <p>20 Q Do you understand that asbestos -- that</p> <p>21 minerals like tremolite or anthophyllite, they</p> <p>22 exist in both the asbestiform and nonasbestiform</p> <p>23 way?</p> <p>24 A I would defer to other experts on the</p>	<p style="text-align: right;">Page 385</p> <p>1 Object to the form.</p> <p>2 A The inclusion of the asbestos, again,</p> <p>3 as -- as -- as we've discussed a few times today,</p> <p>4 the conclusion I developed from the report were</p> <p>5 not dependent or independent of any one or</p> <p>6 another component of -- of the talcum powder.</p> <p>7 As we discussed a bit ago, the presence</p> <p>8 of asbestos as a known inflammatory mediator, as</p> <p>9 well as potential carcinogen, I think just helps</p> <p>10 lend additional support to the biological</p> <p>11 plausibility of the mechanism. But I think that</p> <p>12 biological mechanism is not dependent on the</p> <p>13 presence of asbestos.</p> <p>14 MS. BROWN:</p> <p>15 Q Other than plaintiffs' expert,</p> <p>16 Dr. Longo, are you relying on anything else to</p> <p>17 support the potential for asbestos in baby</p> <p>18 powder?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A There's -- so I saw reference to</p> <p>22 asbestos content in some of the other literature</p> <p>23 that was reviewed during the time, and, so, there</p> <p>24 were other publications that made mention of the</p>

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<p>1 asbestos content in talc during the overall 2 review. 3 MS. BROWN: 4 Q Sitting here today, are you aware 5 whether or not that was Johnson & Johnson's 6 cosmetic talc? 7 MS. O'DELL: 8 Object to the form. 9 A I would have to look closely. I'm not 10 aware of that specifically. 11 MS. BROWN: 12 Q Counsel asked you some questions about 13 Dr. Crowley and whether or not you were relying 14 on the opinions he reached. Do you remember 15 those questions? 16 A I do. 17 Q What opinions did Dr. Crowley reach on 18 which you rely? 19 A Dr. Crowley performed an analysis of 20 the fragrance components and made assessments of 21 the individual chemical components and their 22 relationship to -- or I should say their -- their 23 inclusion on various lists for their -- their 24 chemical properties or safety. And in most -- in</p>	<p>1 opinion is independent of Dr. Crowley's findings. 2 Is that fair? 3 MS. O'DELL: 4 Objection to form. Vague. 5 A Well, my -- my -- my opinion, again, 6 similar to -- as we've been discussing that, it 7 considers the totality of the information 8 available, including Dr. Crowley's report, but 9 does not rely on any one specific report or 10 otherwise. 11 And, so, the -- again, restating 12 similar to the asbestos, the presence of 13 potential irritants as another component in 14 the -- in the product just provides additional 15 support for that inflammatory mechanism playing a 16 significant role. 17 MS. BROWN: 18 Q If none of the chemicals Dr. Crowley 19 identified were present in baby powder, would you 20 hold the same opinion of biological plausibility? 21 A I would. 22 Q If no asbestos was present in baby 23 powder, would you hold the same opinion on 24 biological plausibility?</p>
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<p>1 the majority of cases, the chemicals were not 2 listed. In a number of cases, there were large 3 numbers of chemicals listed as either irritants 4 and, therefore, able to cause inflammation, or, 5 in a few cases, as potential carcinogens. 6 And, so, it was that review of that 7 information, similar to our discussions around 8 asbestos, that I included or agreed with his 9 opinions regarding that on the last paragraph or 10 close to the last paragraph of the report that 11 stated I was just in agreement that these -- that 12 those chemicals contribute to the inflammatory 13 properties observed. 14 Q Do you know in what quantity the 15 chemicals Dr. Crowley identifies are present, if 16 at all, in Johnson & Johnson's products? 17 A No. I wasn't asked to provide that 18 review. I would defer to Dr. Crowley's report 19 regarding any quantitative analysis of those 20 chemicals. 21 Q And, as it relates to your opinion, 22 Dr. Levy, it makes no difference whether 23 Dr. Crowley's list has ten chemicals in 24 Quantity X or five chemicals in Quantity Y. Your</p>	<p>1 A Yes. 2 MS. BROWN: 3 No further questions. Thank you. 4 MS. O'DELL: 5 I have just one follow-up. 6 Or do you have anything -- 7 MR. FERGUSON: 8 Nothing further. 9 MS. O'DELL: 10 Excuse me. I'm sorry. 11 EXAMINATION 12 BY MS. O'DELL: 13 Q Dr. Crowley, are your opinions in this 14 case contained in your report as well as in the 15 testimony that you've given here today? 16 A You said Dr. Crowley. 17 Q Oh. Excuse me. Sorry. I had 18 Dr. Crowley on my mind. 19 Dr. Levy -- 20 It's getting late in the day. 21 Dr. Levy, are your opinions in this 22 case expressed in your report and your testimony 23 today? 24 A Yes.</p>

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<p style="text-align: right;">Page 390</p> <p>1 Q And do you hold those opinions to a</p> <p>2 reasonable degree of scientific certainty?</p> <p>3 A Yes.</p> <p>4 MS. O'DELL:</p> <p>5 I have nothing further.</p> <p>6 MS. BROWN:</p> <p>7 Thanks for your time, Doctor.</p> <p>8 I think we're off the record.</p> <p>9 VIDEOGRAPHER:</p> <p>10 We're off the record. The time is</p> <p>11 6 p.m.</p> <p>12 (Deposition concluded at 6:00 p.m.)</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 392</p> <p>1 ERRATA PAGE</p> <p>2</p> <p>3 I, SHAWN LEVY, Ph.D., the witness herein,</p> <p>4 have read the transcript of my testimony, and the</p> <p>5 same is true and correct, to the best of my</p> <p>6 knowledge, with the exceptions of the following</p> <p>7 changes noted below, if any:</p> <p>8 Page/Line Word(s) to be changed/reason Correct Word</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 SHAWN LEVY, Ph.D.</p> <p>24</p>
<p style="text-align: right;">Page 391</p> <p>1 CERTIFICATE</p> <p>2</p> <p>3 I do hereby certify that the above and</p> <p>4 foregoing transcript of proceedings in the matter</p> <p>5 aforementioned was taken down by me in machine</p> <p>6 shorthand, and the questions and answers thereto</p> <p>7 were reduced to writing under my personal</p> <p>8 supervision, and that the foregoing represents a</p> <p>9 true and correct transcript of the proceedings</p> <p>10 given by said witness upon said hearing.</p> <p>11 I further certify that I am neither of</p> <p>12 counsel nor of kin to the parties to the action,</p> <p>13 nor am I in anywise interested in the result of</p> <p>14 said cause.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19 LOIS ANNE ROBINSON, RPR, RMR</p> <p>20 REGISTERED DIPLOMATE REPORTER</p> <p>21 CERTIFIED REALTIME REPORTER</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 393</p> <p>1 DECLARATION OF WITNESS</p> <p>2</p> <p>3 I, the undersigned, declare under penalty</p> <p>4 of perjury that I have read the foregoing</p> <p>5 transcript, and I have made any corrections,</p> <p>6 additions, or deletions that I was desirous of</p> <p>7 making; that the foregoing is a true and correct</p> <p>8 transcript of my testimony contained herein.</p> <p>9 EXECUTED this _____ day of _____,</p> <p>10 2019, at _____,</p> <p>11 (City) (State)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16 _____</p> <p>17 SHAWN LEVY, Ph.D.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>